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June 2013
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Building A Biologics R&D Engine At MedImmune

"We don't have the 'has-to-be-invented-here' syndrome that you find in some organizations." p. 24

Bahija Jallal
Executive Vice President, MedImmune

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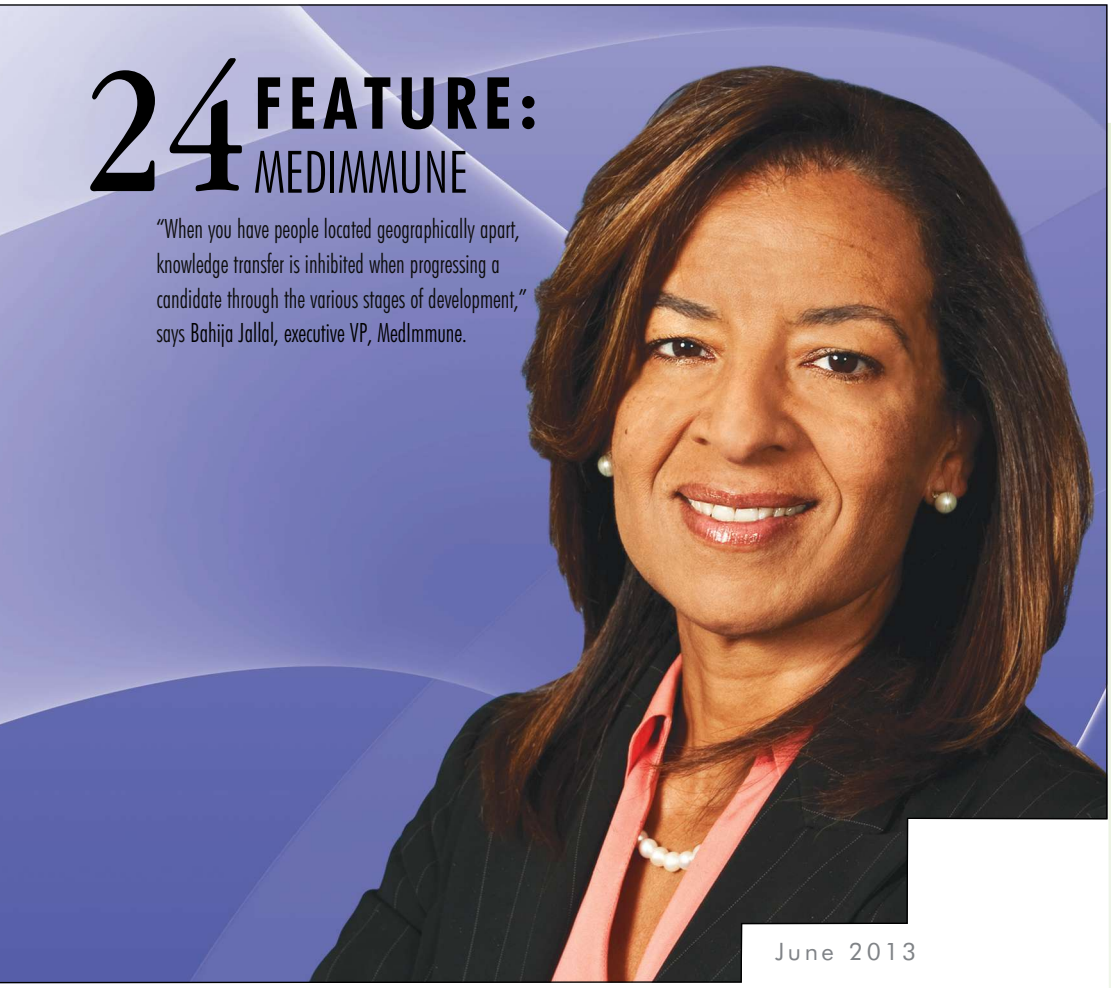

24 FEATURE: MEDIMMUNE

"When you have people located geographically apart, knowledge transfer is inhibited when progressing a candidate through the various stages of development," says Bahija Jallal, executive VP, MedImmune.

June 2013

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EDITOR'S NOTE

Can We Really Trust Emerging Markets To Protect IP?

In December 2012, the U.S. Chamber of Commerce's Global Intellectual Property Center (GIPC) released an index which noted that the four-member emerging economies — Brazil, Russia, India, and China (BRIC) — scored the worst for protecting copyrights, patents, and other intellectual property (IP). The index scored 11 countries on a 25-point scale. Dead last in this index was India (6.24), followed by China (9.13), Brazil (9.57), and then Russia (11.17). The United States scored the highest for IP protection (23.73), and Britain was second (22.4). The reason this is significant is that these countries are negotiating the Trans-Pacific Partnership (TPP) Agreement — a vehicle for Asia-Pacific-wide economic integration intended to strengthen U.S. ties to the robust economies of this region. But for how long can or should biotech and pharmaceutical companies continue to conduct business in regions where there is government-enabled IP theft?

In April, the Supreme Court of India upheld a lower court decision to deny Novartis patent protection for the beta crystalline form of Imatinib Mesylate. Marketed as Glivec in the EU, and Gleevec in the U.S., it is a drug for myeloid leukemia and other kinds of tumors. In its ruling, the court determined that the patent application did not satisfy the tests of invention and patentability. Nearly 40 other countries around the world, including China, Russia, Mexico, and the U.S., disagree, having granted Novartis patent rights for this cancer treatment. The Cancer Patient Aid Association in India responded to the ruling noting, "The court has recognized the right of patients to access affordable medicines over profits for big pharmaceutical companies through patents." I am sure Indian generic drug manufacturing giants Cipla and Natco Pharma will find the manufacture of these and other drugs the Indian government decides to nationalize highly profitable. Ranjit Shahani, managing director of Novartis India, said the company would be cautious about investing in India, especially when it comes to introducing new drugs, and seek patent protection before launching any new products. Further, the company will continue to refrain from R&D development activities there. Can you blame them? Why should companies like Bayer, Roche, and Pfizer, which have lost similar patent protection in India, want to invest in creating drugs with little chance of IP protection? Some have argued that companies within and outside of the life sciences industry should reconsider outsourcing other types of work now done in India to other countries where IP is not only respected, but supported. I agree.

China poses another problem as it is the direct source of two-thirds of the world's counterfeit goods. The United Nations estimates China makes about $5 billion from trafficking fake pharmaceutical products annually. Though Russia and Brazil aren't much better when it comes to IP protection, both India and China seem most inclined to bend the rules however they see fit. China seems incapable of enforcement of illicit behavior, while India takes the position of enabling it. I wonder how long the nearly 55 million Americans (approximately 1/6 of the population) who work in industries that depend heavily on IP rights protection are going to allow this to continue.

Rob Wright
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Some see a map of potential sites.

Covance sees a way to save millions on clinical trials.

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Q: What are the advantages for start-ups of virtual business models vs. biotech incubators?

Choosing between these two "lean" models depends on a host of factors, including funding, timelines, and available resources. Virtual companies must outsource all experimental work to CROs, which requires a team of consultants and project managers and can be more expensive than doing the work in-house. The start-up must give up a level of control over the work, and progress may be slower. Working in a biotech incubator allows companies to "hit the ground running" and have more control over the work and timelines. Both options are definitely more cost-effective than leasing space and outfitting a lab. Some incubators even extend their offerings beyond lab space to include services such as access to investors, pitch coaching, or business development. Any company that does not obtain an immediate infusion of Series A venture capital investment should definitely consider running virtually or within an incubator setting.

Dr. Laura Hales
Dr. Hales has more than a decade of experience in biologics discovery research and is a founder of Extend Biosciences and The Isis Group.

Q: As a small to midsize sponsor company exploring the use of regional/specialty CROs, what 3 internal/external considerations do you feel are most important?

If we are interested in a specialty CRO, we look for demonstrated experience with considerable theoretical and practical expertise in the pharma industry. At the operational level, all support staff within the organization MUST have the experience and expertise. We sometimes use specialty CROs for projects that are challenging due to a combination of timeline constraints and content difficulty, where the flexibility offered is necessary. We aren't interested in using specialty CROs for bread-and-butter projects. Other considerations for selecting a regional CRO include determining if the company has a novel pathway with a proven record of positive interactions with regulators and a proven infrastructure in a geographic region where a more traditional partner may be underresourced.

Dr. Mitchell Katz
Dr. Katz has 26 years' experience in the pharma and biotech industries, including preclinical research, pharma operations, and regulatory affairs. He is the executive director of medical research operations at Purdue Pharma L.P.

Q: What is an example of an emerging therapeutic class of drugs, and what made it possible?

Therapeutic vaccines require definitive identification of pathogenic T cell epitopes. Recent initiatives to optimize immune monitoring have facilitated rational vaccine design. A major limitation, thus far, has been the inability to perform antigen specific immunotherapy (ASIT) in the context of diseases in which the epitopes responsible for pathology are not well-defined, and the tools to accurately monitor the vaccine-associated immune response don't exist. Defining surrogate immunological outcomes that accurately and consistently predict clinical tolerance will accelerate development of this new class of therapeutics for autoimmune diseases that, until now, have relied upon clinical trial primary endpoints. Advances in understanding pathogenic immunodominant epitopes in autoimmune diseases and development of peptide-based ASIT have enabled an emerging therapeutic class of drug, epitope-specific immunotherapy or ESIT.

Leslie Williams
Williams is president, CEO, and founder of ImmusanT, Inc. She has more than 20 years of industry experience in healthcare, management, commercial product development, and marketing.


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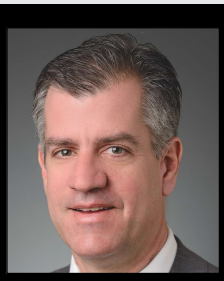
Obamacare Subsidies Will Drive Employers To Drop Coverage

Buried in the President's 2,000-page FY 2014 budget is a table showing the cost of healthcare reform's subsidized coverage in newly created health insurance exchanges will be twice as expensive in 2014 as his budget projected just two years ago. That's right — the President's own actuaries are now conceding health reform will be substantially more expensive than they originally let on.

No explanation is provided for the ballooning estimate. But there are only two possible reasons: 1) per capita cost will be higher; or 2) there will be more individuals accessing subsidized coverage. Certainly, the Supreme Court's decision to make Medicaid expansion optional for states could drive more coverage to the exchanges.

But what about employers' incentives to dump their employees into the exchanges?

Looking back at the tussle over the Affordable Health Act (ACA), proponents of healthcare reform appeared to have drawn a royal flush from the Congressional Budget Office (CBO). CBO speculated that just 8 million of the 162 million individuals with employer-sponsored coverage would lose that coverage and get subsidized coverage in the exchange.



John McManus,
The McManus Group
jmcmanus@mcmanusgrp.com

This was an unbelievably favorable budget estimate because it predicted almost every dollar spent by the federal government would result in an expansion of coverage to the uninsured rather than displace employer-sponsored coverage. It validated the Obama Administration's narrative that most people would keep their current coverage and also tremendously understated the true cost of health reform.

How will employers react when they realize that they can typically save $18,000 for a family policy and only pay a $2,000 penalty so their employees can get subsidized coverage in the exchange?

Most economists would argue the math is not that simple. Employer-sponsored health insurance is exempt from income and payroll taxes; thus, it is, in essence, subsidized by the government. A dollar of health benefits is worth more than a dollar of wages. This tax subsidy is equal to the individual's marginal tax rate, which increases with income.

But what if we compared that tax subsidy to the means-tested subsidy for individuals enrolling in the insurance exchange? Those subsidies are enormous for low-income individuals and gradually phase down as income increases. The ACA limits premiums individuals pay for their coverage to a percentage of their income and requires the government to subsidize the remaining amount up to a benchmark plan (the second cheapest "silver plan" in the exchange). In addition, low-income individuals also receive cost-sharing subsidies.

The table on page 12 shows that premium and cost-sharing subsidies range from almost $18,000 for a family of four making $32,000 a year, to about $4,700 for a similar family making $96,000. Conversely, the employer tax exclusion for a typical policy provides modest benefits for low- and middle-income employees — about $4,700 for those with incomes below $60,000 a year, and greater benefits for those with higher incomes — about $6,100 for those making $100,000 a year.

While an employer cannot decide to drop coverage for some employees and retain it for others, a savvy employer with a low- and or middle-income workforce would soon arrive at a compelling conclusion: It could drop coverage for its employees, direct them to obtain coverage in the exchange, pay the $2,000 penalty, and both the employees and the employer would be better off. The employer could pay the penalty, provide a pay raise that holds the employees harmless by paying for their unsubsidized premium, and still save substantial money.

The net benefit to a large employer for each employee at $32,000 of income would be over $11,000, $7,400 benefit for employees at $48,000, and $2,800 for employees at $60,000 of income. The tipping point when the tax exclusion finally exceeds the subsidies in the exchange occurs at about $65,000 a year in income.

But for a small employer who pays no penalty for failing to offer coverage, that tipping point does not occur until the employee earns $80,000 a year.

According to the U.S. Census Bureau, 58% of households earn less than $60,000 a year, and 79% of households earn less than $100,000. Yet in the face of this math, CBO predicted —as I stated earlier — that only 8 million people, of the 19 million receiving subsidized coverage in the exchange, are in the exchange because they were dumped by their employer.

What if just 10% of those with employer-sponsored coverage lost that coverage and were dumped into the exchange? That would result in a 50% increase of those receiving subsidized coverage, as it would result in another 16.2 million people (10% times 162 million) getting government-sponsored

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coverage. A 20% drop more than doubles the number in the subsidized exchange. The sensitivity analysis is breathtaking. No wonder a McKinsey survey predicts 30% of employers will drop coverage. A different survey of 71 Fortune 100 companies found employers could save $28.6 billion in 2014, which would impact 10.2 million employees and dependents.

The Administration and healthcare reform proponents often fall back on a more nebulous argument — employers offer health coverage to attract and retain workers. Yes, that's certainly the case now. But will that be the case if workers can obtain comparable coverage offered by the government with employers actively directing them to exchange websites and assisting in paying their unsubsidized premiums?

This phenomenon does not have to occur overnight to have a substantial impact. The chaos of the initial implementation of healthcare reform will indeed likely encourage most employers to retain coverage in the short term. A number of other factors unrelated to these subsidies will roil the insurance market.

But even if a minority of employers drop coverage in the next several years, others may be compelled to join them in order to remain competitive. How would Verizon and AT&T respond if Sprint were able to substantially cut its cost by dumping workers into the exchanges and started cutting its rates? How would large chain pharmacies respond if a company like Walgreens created a subsidiary to provide employer-sponsored coverage to its high-paid pharmacists and a different subsidiary employing low-paid clerks who were shuffled off to the exchange for their healthcare?

The momentum for employers to offer coverage to hire and retain coverage will be reversed.

The long-term impact of such a phenomenon?

- substantially higher government spending than was originally contemplated
- more individuals enrolled in government-regulated plans instead of employer-sponsored insurance
- strange new business models to exploit the new subsidies and escape the $2,000 penalty
- more government scrutiny on per-unit costs of healthcare goods and services to help contain rising health obligations.

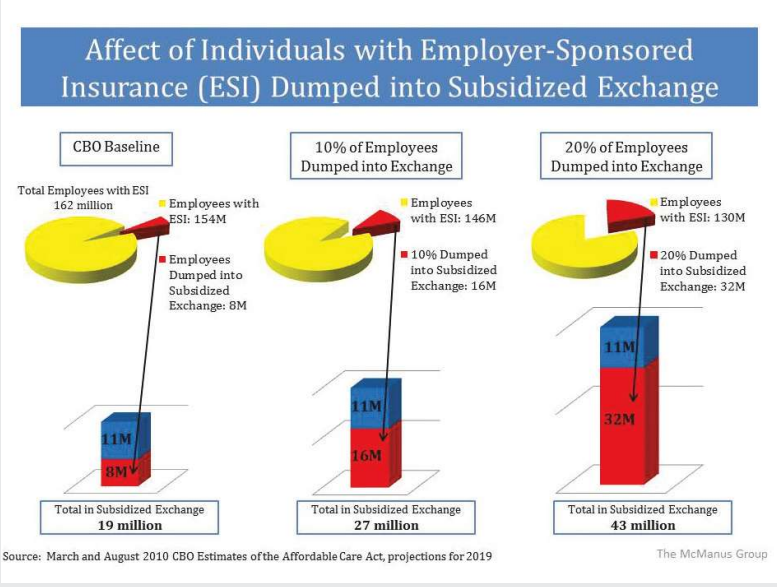
Businesses with 50 or More Employees, Employee with Family of 4

Income	Employee tax benefit	Employer tax benefit	Subsidy in Exchange	Combined Benefit to Employer & Employee if Drop Coverage [(subsidy in the exchange – employer & employee tax benefit) – ($2k employer penalty)]	Employer Decision?
$32,000	$3,723	$1,030	$17,924	$11,171	Drop
$36,000	$3,723	$1,030	$17,121	$10,368	Drop
$48,000	$3,723	$1,030	$14,151	$7,398	Drop
$60,000	$3,723	$1,030	$9,576	$2,823	Drop
$72,000	$5,069	$1,030	$6,969	($1,130)	Keep
$96,000	$5,069	$1,030	$4,685	($3,415)	Keep
$100,000	$5,069	$1,030	$0	($8,100)	Keep

2014 "Silver Plan" Premium Value = $13,824

2014 Employer Premium = $13,465 ($17,953 plan cost x 75% contribution)

Source: CBO and JCT projections for typical family of four health insurance in 2016 modified by National Health Expenditures per capita growth rate



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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Winner of the 2012 CRO Leadership Award for quality, regulatory, reliability, productivity and innovation.

By Wayne Koberstein, executive editor

Cempra

Novelty and practicality blend in this company's drive for antibiotics innovation.

SNAPSHOT

Cempra is one of a rare but expanding breed of companies answering the call for new antibiotics. Its two lead products, solithromycin (CEM-101) and Taksta (CEM-102/sodium fusidate), go at the challenge of antibiotic-resistant bacteria in two different ways — with a novel drug in the first case and with a novel form of an old drug in the second. Solithromycin is a new-generation macrolide and "the first fluoroketolide," which is active against macrolide-resistant bacteria and more active than azithromycin or clarithromycin against most macrolide-susceptible bacteria, according to the company. The novel compound (in oral form) is in a global Phase 3 clinical trial in patients with community-acquired bacterial pneumonia (CABP). Taksta is an older antistaph drug, active against MRSA, recast into a "loading dose formulation" designed to "maximize efficacy and bacterial coverage while minimizing resistance development."

Prabhavathi Fernandes, Cempra

LATEST UPDATES

• *May 2013:* Cempra signed a license and development partnership with FUJIFILM's Toyama Chemical for commercialization of solithromycin in Japan.

• *December 2012:* Initiated an oral solithromycin (CEM-101) global Phase 3 clinical trial in CABP, and a Phase 2 clinical trial of Taksta (CEM-102/sodium fusidate) in patients with prosthetic joint infections.

• *October 2012:* Obtained positive top-line results from solithromycin Phase 2 clinical trial in uncomplicated urogenital gonorrhea.

WHAT'S AT STAKE

Depending on your definition of "novel," a few other companies may be considered more innovative than Cempra for inventing entirely unprecedented classes and MOAs (mechanism of actions), which are also oft-disputed terms. But novelty is as novelty does. New treatments that actually work to cure patients, while defeating or slowing microbial resistance, will ultimately define the term. If Cempra succeeds where others fail, its practical blend of NCE and dosage-form development will deserve credit.

According to Cempra Founder, President, and CEO Prabhavathi Fernandes, the climate for new antibiotic development continues to improve. "Although many large pharmaceutical companies have exited the antibiotic space, other commercial-stage companies, such as Forest Laboratories, Cubist, and Astellas, continue to invest. But antibiotic development, particularly for targeted indications, is more feasible for small companies than is drug development for major chronic diseases." Because the needed studies are of relatively short duration — cures usually occur within two weeks — the overall cost of the clinical trials is much lower compared to those for oncology drugs or other drug candidates that take longer to reach clinical endpoints, she explains. "Finally, it is feasible for small companies to commercialize their antibiotics if the hospital rather than the community is the point of sale."

Governments have also given the sector a shot in the arm. Public and public/private initiatives in Europe, followed by the GAIN (Generating Antibiotic Incentives Now) Act and new-guidance drafting by the FDA, have boosted financial incentives and are clearing the path for new antibiotics aimed at resistant bacteria.

"We are very focused on developing differentiated antibiotics with the right spectrum that are effective against the pathogens causing a disease, including against drug-resistant strains," says Fernandes. "Solithromycin has the right spectrum of activity for CABP because it is active against common CABP pathogens, such as Streptococcus pneumoniae, as well as atypical pathogens such as Legionella." Its wide spectrum may allow its use as monotherapy, and its availability in oral and intravenous forms can allow earlier patient release.

If you're looking for the next blockbuster, a wise place might be the antibiotics sector. Fernandes points out the precedent set by former blockbuster antibiotics — such as azithromycin, clarythromycin, and ciprofloxacin — that met not only the safety and efficacy criteria, but also covered the right spectrum for their indications. Another attractive advantage of antibiotics: When they work, they cure. Unlike antineoplastics and other prophylactic drugs, the clinical results for antibiotics are always clear and unambiguous.

VITAL STATISTICS

• Employees: 31; Headquarters: Chapel Hill, NC

• Finances: A Round: $14 million in August 2006; C Round: $46 million in May 2009; IPO: $54.7 million, including over allotment, in February 2012; PIPE: $25 million, in October 2012.

• Partnerships: Curetis AG; collaborating on detection of pathogens in patients enrolled in the oral Phase 3 trial of solithromycin in CABP. Exclusive agreement with Toyama Chemical Co., Ltd., a subsidiary of FUJIFILM Holdings Corporation, to develop and commercialize solithromycin in Japan.

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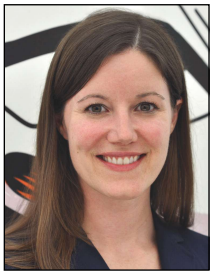

OUTSOURCING INSIGHTS

Trends In Outsourcing — What's Going On In Big Pharma

By Kate Hammeke, director of marketing intelligence, Nice Insight

It should come as no surprise that, when looking for new trends in pharmaceutical development and outsourcing, the industry giants often referred to as Big Pharma are the most popular topic of interest. Big Pharma has been a leader in identifying ways to maintain or improve profitability while simultaneously making efforts to speed up the process of bringing new drugs to the market. While these giants receive their share of flak (oftentimes from the media inciting the general population), they are also a source of inspiration and guidance for the biopharmaceutical industry and a signal of what's to come.

As such, Nice Insight reviewed the behaviors and preferences among Big Pharma respondents who participated in the pharmaceutical and biotechnology outsourcing survey over the past two years. Big Pharma comprised 29% of the respondent base in 2012 and 30% in 2013. Two key data points came from the profile information collected on Big Pharma that will benefit CROs and CMOs that offer drug development services. The first is that outsourcing expenditures increased from 2012 to 2013, with a 6% uptick in companies that spend in excess of $50 million per year — from 49% to 55%. The second is that the average number of unique services outsourced increased from 4 to 6*. Both of these factors indicate that Big Pharma is maintaining its stance on outsourcing as a cost-savings strategy.

OUTSOURCED SERVICES ARE INCREASING

Complementary to the rise in spending and increased number of services outsourced, 11 of 19 outsourced services tracked in the survey showed an increase of 5% or more among Big Pharma respondents. Seven more services showed an increase from 1% to 4%, and only one — fill finish — showed a slight decrease (-2%) in demand as compared to last year. Clinical research revealed the highest increase of 13%, up from 33% in 2012 to 46% in 2013. Clinical research was followed by analytical testing, which rose 9%, from 34% to 43%, and bioanalytical testing, which climbed 8% from 26% in 2012 to 34% in 2013. Process optimization and product characterization also showed an increase of 8%. However, despite this increase, fewer than one in five Big Pharma respondents will engage an outsourcing partner for process optimization or product characterization in the next 12 months.

Data collected through Nice Insight's strategic partnering studies revealed the top motivations for outsourcing among Big Pharma respondents are improved quality (54%), improved time-to-market (49%), and decreased fixed costs (45%). While the annual research data reiterates Big Pharma's continued reliance on outsourcing as a means for cost savings, there was a notable change in the way Big Pharma prioritized Nice Insight's six outsourcing drivers: affordability dropped from third place in 2012 to fifth place in 2013, having fallen behind regulatory and productivity. It is doubtful that this change in rank means Big Pharma spending will be unleashed; rather, it is likely an indication that lower prices are not a substitute for imperfect regulatory compliance or reduced productivity.

In addition to the differences in outsourcing behaviors from 2012 to 2013, there were some differences in how Big Pharma engages CROs and CMOs. Most notably, Big Pharma respondents expressed a stronger interest in forming strategic partnerships with CROs — 9 out of 10 said they are interested as compared to 8 out of 10 expressing interest in a CMO strategic partnership. To further this notion, Big Pharma respondents admitted there is a greater likelihood for a CRO that started off as a tactical provider to become a preferred provider — 92% as compared to 72% for CMOs. This disparity continued when asked about the likelihood of a preferred provider becoming a strategic partner; 87% of Big Pharma respondents agreed it is likely for a CRO as compared to 69% who agreed it is likely for a CMO.

If your business is looking to partner with Big Pharma, understanding this customer group's outsourcing motivations and needs will aid in creating customized communications that specifically address those needs. As a drug innovator, it may make sense to consider how the outsourcing strategies employed by Big Pharma would work for your business.

** out of the 19 services covered by the Nice Insight survey during 2012-2013*

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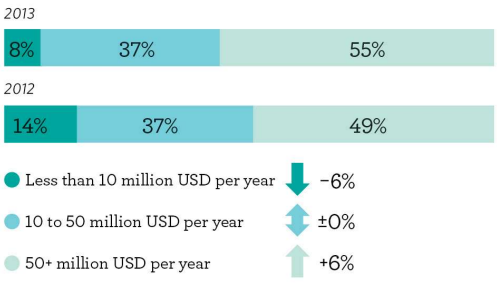
BIG PHARMA: Services Outsourced

	2013	2012	Change
Clinical Research	46%	33%	13%
Analytical Testing	43%	34%	9%
Bioanalytical Testing	34%	26%	8%
Regulatory Support	29%	24%	5%
Chemical Synthesis	25%	20%	5%
Custom Manufacturing	24%	23%	1%
Drug Delivery	24%	22%	2%
Logistics & Distribution	23%	20%	3%
Toxicology Testing	23%	16%	7%
Stability, Storage & Testing	21%	18%	3%
Fill and Finish	19%	21%	-2%
Blending	18%	15%	3%
Product Characterization	18%	10%	8%
Process Optimization	18%	10%	8%
Formulation / Pre-formulation	16%	11%	5%
Sterile Compound R&D	16%	10%	6%
Cytotoxic	15%	8%	7%
High Potency Compounds	12%	11%	1%
Lyophilization	11%	8%	3%
Average # of Unique Services Outsourced	6	4	

Annual Outsourcing Expenditure



Outsourcing Drivers in Ranked Order of Importance

2013		2012
1	Quality	1
2	Reliability	2
3	Regulatory	4
4	Productivity	5
5	Affordability	3
6	Innovation	6

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

CMOs Leading The Way In Biopharma Innovation — No Herd Mentality

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

Innovation is often driven by the end users most in need of new and better technologies and tools. In biomanufacturing, the CMOs are often the most active scouters seeking better, more cost-effective ways to support their clients' needs, differentiate themselves from other CMOs, and remain more efficient and competitive. CMOs, therefore, are a leading indicator of future trends and what new technologies are to come.

This year at the BIO meeting in Chicago, we sought out 10 globally recognized CMOs to determine how they are implementing novel technologies today and how these will impact future bioprocessing for all biomanufacturers. We asked, "Where are CMOs investing in new technologies that will improve bioprocessing today and over the next five years?" We were surprised at the breadth of innovation being adopted and the fact that none of the CMOs are handling new technology adoption the same way. This is likely to accelerate new manufacturing methods and breed more and better approaches — something often lacking in this generally conservative, regulations-bound industry.

Below is a summary of new technology offerings listed alphabetically by company. Much of the innovation at CMOs is not associated with individual technology adoption but rather the integration of multiple novel approaches that create improvements synergistically. A number of world-class CMOs are absent from this list, but we believe comments are representative of the industry at large.

AMRI Global (Albany, NY) "We consider innovation on the fill/finish side of the CMO process to be most important to our clients. At AMRI, we have invested in drug-delivery technology. For example, our prefilled, bubble-free syringe technologies enable predosed, easier, faster use and greater patient compliance. This is the future of fill/finish." *Daniel Conlon, senior director of business development*

Boehringer Ingelheim Pharma (Biberach, Germany) "We are integrating new technologies, such as column-free downstream processing to replace protein A, and continuous-downstream processing technologies that can reduce time-to-clinic and time-to-market significantly. This focus on speed is where CMOs need to direct efforts today and in the future." *Dr. Alexander Jung, senior manager, BD Technologies*

CMC Biologics (Bothell, WA, and Copenhagen, DK) "We are especially focused on integrating new upstream technologies, including our CHEF1 expression system for mammalian production, with our active development programs for perfusion and other continuous bioprocessing. By continually increasing upstream productivity, our clients find they can reduce overall costs in clinical and later on in commercial-stage production." *Morten Munk, VP business development*

Cook General BioTechnology (Indianapolis) "The biotechnology industry today is seeking innovation for container systems in cryopreservation, and we currently have a completely closed-system cryogenic vial. Also, we are actively developing an automated filling system for disposable vials permitting scalability and aseptic practices while maintaining cell quality." *Dr. Erik Woods, Ph.D., president and CEO*

DSM (Portsmouth, NH) "We are introducing innovative technologies particularly in up- and downstream process intensification. For example, we combine our upstream XD technologies and simpler downstream processing via our Rhobust technology for the direct capture of proteins. Together, these technologies enable pharma companies to reduce costs and will permit companies in emerging markets to produce biologics domestically with limited capital expenditure." *Tom Hindle, senior director, business development*

Fujifilm Diosynth Biotechnologies (Billingham, UK) "The biopharma industry needs more than just incremental technology improvements. Advances are very complex, and the value is in integrating the various component technologies into a logical and simplified solution. For example, evaluating and selecting the right technologies associated with antibody drug conjugate development and manufacturing requires in-depth knowledge of each technology and how they will fit together to deliver a better overall solution." *Mark Douglas, director, strategic business development*

Laureate Biopharma (Princeton, NJ) "We've invested in new single-use fill/finish technologies. We employ filling technologies where all product contact equipment is single-use. By going 100% disposable, we are eliminating the need for cleaning validation. This virtually eliminates associated cross-contamination risks and keeps costs down. Clearly,

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the future of innovation is in these single-use technologies." *Robert Broeze, chief commercial officer*

Lonza Custom Manufacturing (Allendale, NJ) "One critical area of investment today is in the overall facility design for scale-up of new process platforms, such as antibody drug conjugates (ADCs) with novel linker/payload technologies. Beyond just the linker technology, CMOs need to provide the scale-up capabilities for ADC production. Combining the antibody and the cytotoxic is important, but designing a commercial-scale process around the technology is even more vital. This is an opportunity for CMO process design."

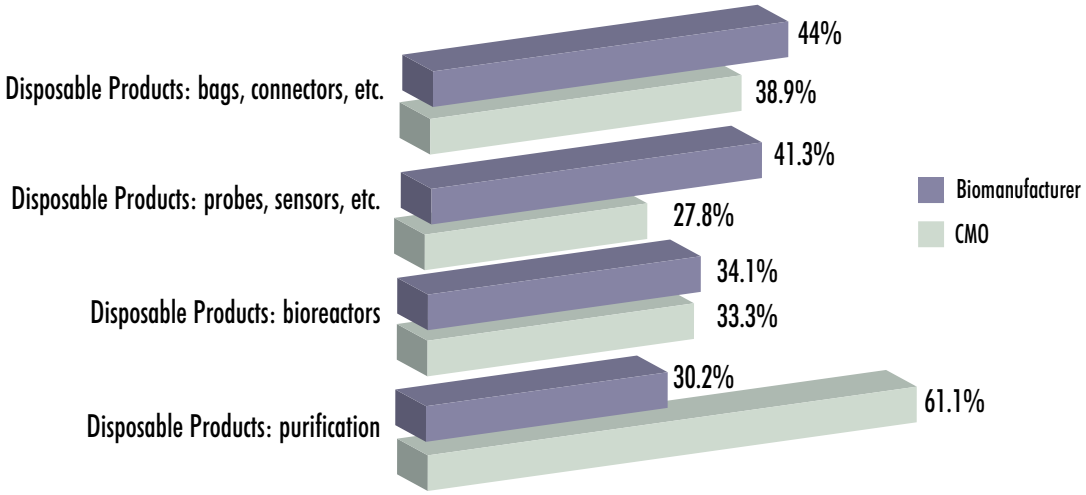
Rentschler Biotechnologie (Laupheim, Germany) "Innovation is vital to any CMO. For example, at Rentschler, we feel that speeding the evaluation process in the early stages of development is critical. We developed our TurboScreen stable CHO system to provide faster results, reaching stable clones in only nine weeks using a parallel selection process." *Erik Laursen, director of business development*

Therapure Biopharma, (Mississauga, Ontario) "The innovation in the biopharma CMO industry involves integration of modular approaches to manufacturing — flexible spaces, clean rooms, RAB systems, disposables, and single-use technology, all of which are scalable and permit carrying of a campaign all the way from preclinical to commercial scale, all in the same facility. This reduces tech transfer costs and risks while speeding up the development process." *Safa'a Al-Rais, director of project management*

In our 10th Annual Report and Survey of Biopharmaceutical Manufacturers, we measured 21 different areas where new product development was sought. We evaluated the categories by biomanufacturer (drug innovators) vs. CMOs. We found significant differences in responses. For example, regarding standard, common bags and connectors, CMOs already had implemented these devices years ago and are now seeking innovation in emerging areas such as single-use purification.

By using CMOs as a leading indicator and tracking how they are integrating innovative new technologies and evaluating their adoption strategies, we can project where many of these new technologies will be in two to five years within the overall industry.

New Product Development Areas Of Interest — Biomanufacturers vs. CMOs



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.

If you want to learn more about the report, please go to bioplanassociates.com.

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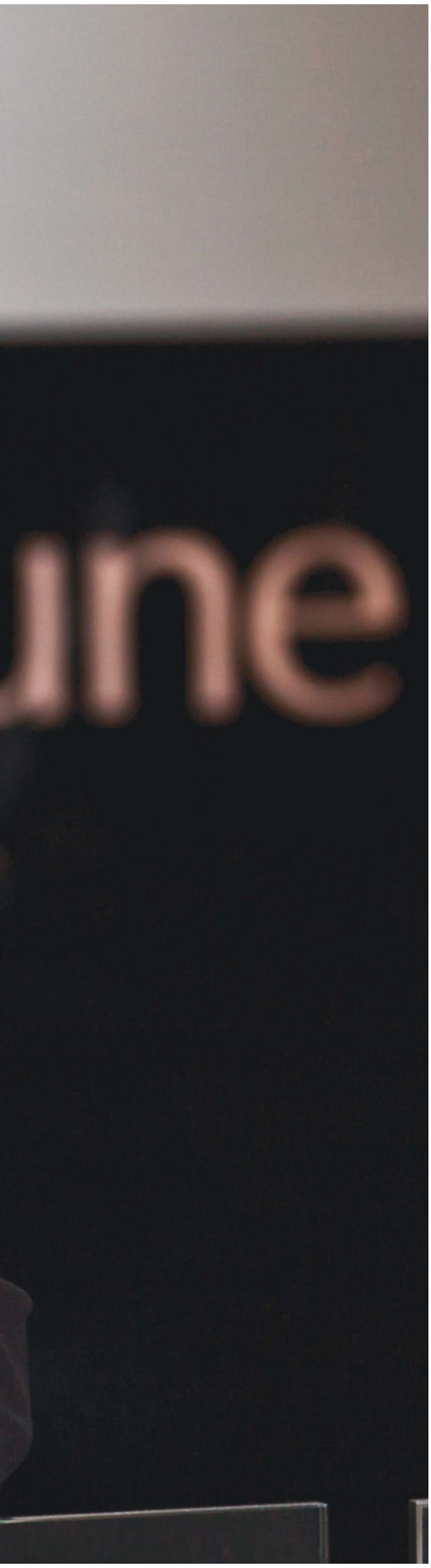
Bahija Jallal, executive VP, MedImmune



MedImmune's Blueprint For Building A Biologics R&D Engine

By Rob Wright

WHEN I SAT DOWN WITH BAHIJA JALLAL AT THIS YEAR'S Bio International Conference in Chicago, the new leader of MedImmune surprised me with her sense of humor. I was telling her about my fondness for unique names and inquired as to the country of origin of "Bahija." In a dead-pan reply that even Carol Burnett would have been proud of, she stated, "It's Swedish." Laughing — because I actually bought it — Jallal went on to explain that she grew up in Morocco before studying in France and Germany and working on both the West and East Coasts of the United States. I quickly learned that Jallal thrives on change, something she experienced relatively quickly after joining MedImmune in 2006 as the VP of translational sciences.

Just one year into her position at the Maryland-based biotech, the company was acquired by AstraZeneca (AZ) for a whopping $15.6 billion. Under her watch, Jallal guided MedImmune's R&D biologics pipeline from 40 drugs to 140+. That track record didn't go unnoticed by AZ's newly appointed CEO, Pascal Soriot. In what some described as a management shake-up, Soriot, who joined AZ last August, announced earlier this year that MedImmune would be taking center stage as AZ's biologics R&D center — elevating Jallal to executive VP (the top position at the company, a position previously held by Peter Greenleaf). According to Jallal, the move is designed to more fully integrate MedImmune into AZ, with the former commercial and manufacturing operations being folded into the parent company instead of operating as a subsidiary. "What changed," says Jallal, "is I now report directly to the CEO of AZ, elevating the biologics business to the executive suite." The move makes sense when you consider MedImmune's biologic pipeline has gone from 5% to half of AZ's current portfolio. If biologics are taking on a more prominent role within your organization, Jallal has some insights on how to successfully focus your biologics R&D operation so as to encourage, not kill, the entrepreneurial spirit on which it was built.

THE BENEFIT OF CONSOLIDATING EARLY- AND LATE-STAGE DEVELOPMENT

In the real estate industry, the three most important things to buying or selling a piece of property are — location, location, and finally location. The same principle applies when building a productive biologics R&D organization. For AZ, the decision to focus its biologics drug development business in Gaithersburg (the fourth largest city in Maryland) may seem odd when the most well-known biotech hubs in the United States are in California and the greater Boston area. "When planning where you want to be, you really need to plan for the long term," she states. "Sure, having close access to talent, universities, and other biotechnology companies are key components to a company's innovation ecosystem, but there are other things to consider as well." Being in Gaithersburg places MedImmune within close proximity to universities such as Johns Hopkins and approximately 131 other biotechs. It also places it within 15 minutes of Bethesda, MD, home to the main campus of the NIH and the Walter Reed National Military Medical Center. This location also is within 20 miles of the FDA and 30 miles from the nation's capital. But the decision to centralize in Gaithersburg had other advantages as well.

Prior to this move, MedImmune's early-stage research was conducted in Gaithersburg and late-stage research was conducted in Wilmington, DE. Though only a two-hour commute between the two cities (on a good day), Jallal believes that keeping the two processes separate was not an effective structure. "In the next two years, there are several projects moving into later stages," she asserts. "When you have people located geographically apart, knowledge transfer is inhibited when progressing a candidate through the various stages of development." By having late-stage development integrated to where the biologic initially evolved, Jallal believes it will make the development progression between stages more seamless, improve productivity, and increase internal collaboration. But along with improved internal collaboration, she wanted to increase external collaboration as well.

SOMETIMES LESS IS MORE

When AZ acquired MedImmune, it began significantly investing in growing it from a smaller company to where it is today. The result has been a threefold increase in the biologics pipeline. Jallal cautions that such rapid success can sometimes make you complacent. "When you are growing, you cannot take for granted that you can keep that level of innovation going," she states. "You really have to do something that entices scientists to continue to be innovative." One of the things MedImmune has done, quite deliberately, is to size the organization a little bit smaller than expected. For example, MedImmune currently has around 2,500 employees globally — a figure that is not much different from when it was acquired in 2007. According to Jallal, this limiting of internal resources forces

CREDIBILITY IS KEY TO COMMUNICATION

In her leadership role as executive VP of MedImmune, Bahija Jallal is responsible for biologics R&D and clinical activities. She believes being a scientist at the top of a scientifically driven organization brings credibility. "In any tough decision that you're going to make, you need to have credibility that you are still associated with the science," she affirms. "I think one of the mistakes we make is when we move from the bench into a leadership role, we tend to take the approach of becoming a manager of scientists. That's not the right way to look at it. As a leader, you have to keep on the cutting edge so that when you make decisions, you are actually explaining why, from a business point of view, which is grounded in scientific understanding." For Jallal, that means working on one "pet project" each year that keeps her hands in the science, in addition to reading scientific literature and publishing papers.

According to Jallal, one of the key things she learned early in her career is the importance of communication. "There is power in being able to explain the entire 'food chain' from a business and scientific perspective," she states. "It brings the understanding of why we're developing whatever we're developing, why we have to make decisions, and why we have to make trade-offs." Jallal believes people are very reasonable when things are well-explained and they understand the why behind a decision. "One of the worst things you can do is to assume that just because a decision in your mind makes complete sense, you don't need to take the time to communicate and explain it to people. If you do that, you won't get buy-in." Her advice is to keep your science sharp, as it not only gives you credibility, but helps with communication. "That's a really big lesson that I learned," she confides. "When you communicate more about why you're making a decision, it creates buy-in, bringing people with you much more so than just sending a memo saying, 'This is what we decided.'"

"You have to remember that you still work for a business, and you need to strive for balance between the business and the science."
Bahija Jallal, executive VP, MedImmune

the MedImmune scientists to collaborate with the outside. "I think that's the essence of keeping the scientists at the cutting edge of what they do best, which is to innovate and do good science," she affirms. It is hard to argue with the results. About 40% of the current MedImmune pipeline consists of external collaborations and partnerships, including a joint development and commercialization agreement with Amgen on five monoclonal antibodies from Amgen's clinical inflammation portfolio, giving MedImmune the most robust inflammation pipeline in the industry. "We don't have the 'has-to-be-invented-here' syndrome that you find in some organizations," she says. Jallal's advice on maintaining your company's entrepreneurial spirit — keep your organization deliberately small as you grow. Another key to creating and maintaining the entrepreneurial spirit within your organization, according to Jallal, is to include the establishment of lofty goals. "For instance, five years ago we said that by 2016 — and at the time we had very few programs in the pipeline — we were going to have one BLA [biologics license application] every year in a sustainable fashion." She says they then worked backwards from the goal to determine how they could achieve it while keeping science and patients as the focus. Focusing on external collaboration, while having a smaller staff, was one component to achieving the goal. Another was implementing HR policies which emphasized and rewarded publications and patents. "We made this part of the MedImmune career progression path for scientists," she states. For an example of this, you need to look no further than Jallal herself — author of more than 70 peer-reviewed publications and holding more than 15 patents.

PUT SCIENCE AT THE CORE AND SIMPLIFY

When I was concluding our discussion, I asked Jallal for a couple of pearls of wisdom for those readers seeking to grow their biologics business with the same level of success as MedImmune's. She told me that the core of any strategy has to be about the people and the science. You need to have scientists who thrive on challenges and are passionate about their science, yet rigorous in their decision making. For MedImmune, this means having an effective governance process. For instance, the team has to be willing to walk away from a project when they know it isn't going to work. "You have to remember that you still work for a business, and you need to strive for balance between the business and the science," she says. That being said, Jallal firmly believes science must be at the core. "To be able to publish and be open to the outside and collaborate is the way to go," she affirms, adding that science is something that can only flourish when you are sharing it and having other people think about the same problems.

The move by Pascal Soriot to consolidate AZ's R&D into three strategic units — U.K., the U.S., and Sweden — has the hefty price of $1.4 billion. Annualized benefits of the overhaul are expected to reach approximately $190 million by 2016. There are other anticipated benefits such as improved productivity and better communication resulting from the reduction of managerial layers. For example, the executive team, which represents the entire R&D engine of the $28 billion, 51,000-employee-member company, is now represented by three people, including Jallal, all of whom report directly to the CEO. Jallal gives credit to Soriot for creating a sensible organizational structure and a simplified strategy. Now, it is up to her to execute on the vision for MedImmune to continue to serve as a blueprint for how to build a biologics R&D engine at a Big Pharma company.

Sustainability To Drive Revenue Growth And Cost Reductions

By David Linich

If sustainability is not on a life sciences company's radar screen, it really should be. No longer just a corporate responsibility issue, adopting sustainable business practices that decrease the amount of water, energy, and other resources used in R&D, manufacturing, and the transport of medical products has become a nuts-and-bolts financial issue. In addition to being well aligned with the current budgetary belt-tightening of many corporations, sustainable business practices are now on the agenda of the major group purchasing organizations (GPOs), one of the most influential external stakeholders in the life sciences industry.

According to a 2012 research study commissioned by Johnson & Johnson, five of the largest GPOs (Amerinet, HealthTrust, MedAssets, Premier, and Novation), which each year collectively buy $135 billion of medical products for hospitals, pharmacies, and other end users, have adopted a sustainability scorecard — a standardized questionnaire to measure a life sciences company's commitment to reducing the consumption of natural resources and production of carbon and waste during a medical product's life cycle (i.e. from raw materials to end-of-life disposal). While the scorecard's 13 questions initially are intended to motivate life sciences companies to reduce their waste, carbon footprint, and use of resources, there is no doubt that if GPOs decide to purchase from a competitor because it has a higher sustainability score, your company's near-term revenue growth opportunities could be affected.

Despite its role in achieving cost savings, risk reductions, and revenue growth, sustainability has not yet been fully embraced in the life sciences industry as widely as it has been in the consumer products industry where stakeholders and consumers were more vocal and demanding. The GPOs' sustainability scorecard provides a strong impetus for action in the industry.

SUSTAINABILITY TIPS

As an advocate for sustainable business practices for Deloitte and its life sciences industry clients, I offer the following observations and considerations:

- Change the dialogue. Because many leaders are put off by the terms "sustainability," "carbon," and "green," avoid using these and other polarizing words when communicating to C-suite executives and board members. The conversation instead should focus on the financial value. Emphasize the cost reduction and risk reduction benefits from being more efficient with scarce resources. Protecting and growing revenue also tends to resonate with leadership, and now that major customers are factoring financial value into their purchasing, it could provide a nice platform for gaining interest from leadership.
- Baseline your performance. An important first step should be to measure where you are today and uncover opportunities for improvement. Based on the results, an action plan and priorities should be identified and "blessed" by the C-suite and board. The company's progress should be regularly monitored and reported, and new opportunities should be identified over time as improvements occur.
- Draw upon advanced analytics. Forward-looking life sciences companies draw upon analytical techniques such as measuring greenhouse gas emissions (including scope 3 emissions) and conducting life cycle assessments (LCAs) to uncover the "low-hanging-fruit" opportunities to advance sustainable practices in their organizations. LCAs measure the environmental impacts of a product from raw materials to end of the product's life, and these analyses surface "hot spots" of opportunity that can unlock cost savings and product innovations that can drive revenue as well.
- Collaborate with suppliers. While LCAs often yield a few quick solutions that can be implemented readily, most of the major wins can require collaboration across functions and with suppliers. However, working with supply chain partners to identify and capture opportunities to develop more sustainable products can be tricky business. Few organizations actively collaborate with their suppliers, yet those that do benefit. A 2012 survey (Deloitte Consulting LLP, in conjunction with ASQ, Institute for Supply Management, and Corporate Responsibility Officer Association) of about 1,000 supply chain executives revealed that companies that engaged with suppliers at any tier were

38% more likely to achieve or surpass their expectations and reduce costs as a result of their initiatives.

• Elevate and expand the responsibility for results. Too often, responsibility for sustainability is delegated too low in the hierarchy and is confined to one particular function, and not surprisingly, the results are limited. Leading companies have equipped the board with oversight and instilled responsibility in the C-suite. Importantly, responsibility and goals for sustainability are cascaded into various functions throughout the organization.

• Capture value from green chemistry and product packaging. Green chemistry, also referred to as sustainable chemistry, is the design of products and processes that reduce the use and production of hazardous substances, by-products, and waste, particularly volatile organic solvents, not just during drug development but also at end-of-life product disposal. Green chemistry, which also emphasizes the adoption of less energy- and materials- intensive processes, can result in substantial cost savings and reduce a company's negative impact on the environment.

PMI AND GREEN CHEMISTRY

Merck, which has received three annual Presidential Green Chemistry Awards from the U.S. Environmental Protection Agency, now calculates the process mass intensity (PMI) — the kilograms of raw materials used to produce one kilogram of pharmaceutically active product — as an indicator of process efficiency, according to a company news release. PMI is calculated for all steps, including those conducted by external suppliers in the development of medical products. The goal is to drive process intensification and waste minimization prior to the launch of new products. Measuring PMI also has become a standard sustainability practice of several other major pharmaceutical companies, including the members of the American Chemical Society's Green Chemistry Institute Pharmaceutical Roundtable, established to create green chemistry tools and support research on applying green chemistry to pharmaceutical discovery and production processes.

PACKAGING REDUCTION

In addition to green chemistry, product packaging is a hot button topic for life sciences companies. Large and costly amounts of plastic, foils, and cardboard traditionally have been used to protect drugs and other medical products and prevent spoilage and degradation during shipment. To minimize the use of insulated boxes and ice packs in the packaging of temperature-sensitive drugs during transport in France, Sanofi several years ago began shipping these products in refrigerated trucks. These vehicles, which carry products between +2° and +8°C., signifi-

cantly reduced Sanofi's packaging costs and the amount of time and money that customers had to spend to break down the boxes and dispose of material that could not be recycled.

Using temperature-controlled trucks instead of temperature-controlled packaging saved Sanofi $28 per package and decreased overall exterior package weight by 15 tons. It also reduced downstream inventory space and materials handling time.

Before switching to refrigerated trucks for transport of its temperature-sensitive drugs in France, Sanofi extensively evaluated various alternatives for reducing the packaging materials for these medications.

Deloitte helped another pharmaceutical company conduct a life cycle assessment in support of a shift in primary packaging from glass to plastic, which had a lower cost and environmental impact profile. In addition to the cost benefits, their sustainability focus generated a lot of positive buzz and visibility for the company.

Most sustainability efforts in life sciences to date have focused on energy efficiency within their "four walls," with fairly noteworthy results. Pfizer recently issued a news release to report that it had achieved $85 million in cost savings during 2008 to 2012 by improving energy efficiency at its facilities. GlaxoSmithKline has announced that it will save $160 million annually in reduced energy, materials, and distribution costs as it works toward its goal of becoming a carbon neutral value chain by 2050.

Forward-looking life sciences companies are shifting their focus outside their four walls and are collaborating with others to improve packaging and product formulation. Not only are these companies poised to realize cost reductions, but they are also poised to protect and grow revenue by scoring well on the GPOs' sustainability scorecard.

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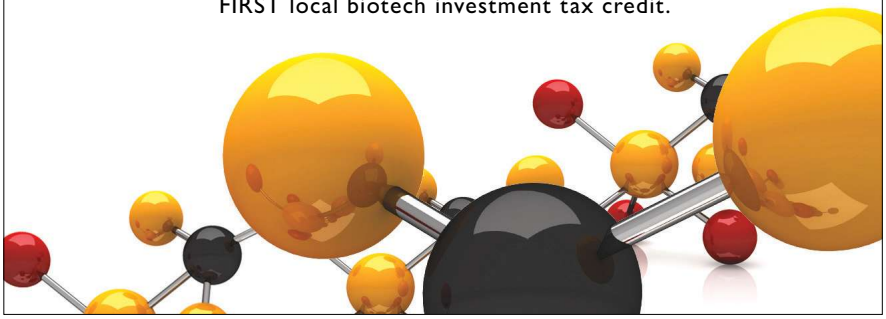

About the Author

David Linich is a principal in Deloitte Consulting LLP's Strategy & Operations practice, where he leads the U.S. operations and supply chain sustainability services. He works with his clients to reduce costs and risk and to grow revenue from sustainability and resource efficiency efforts.

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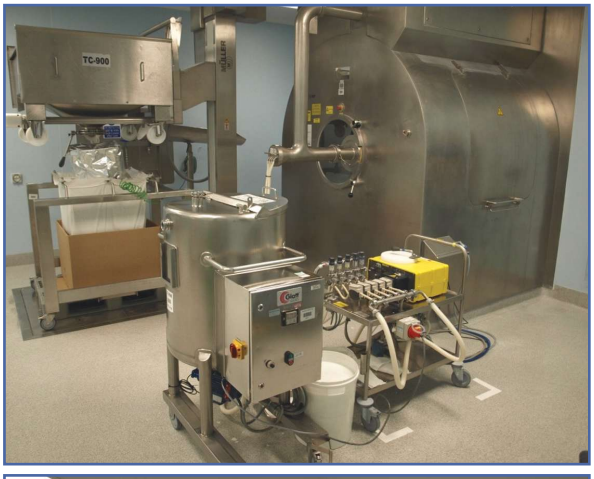

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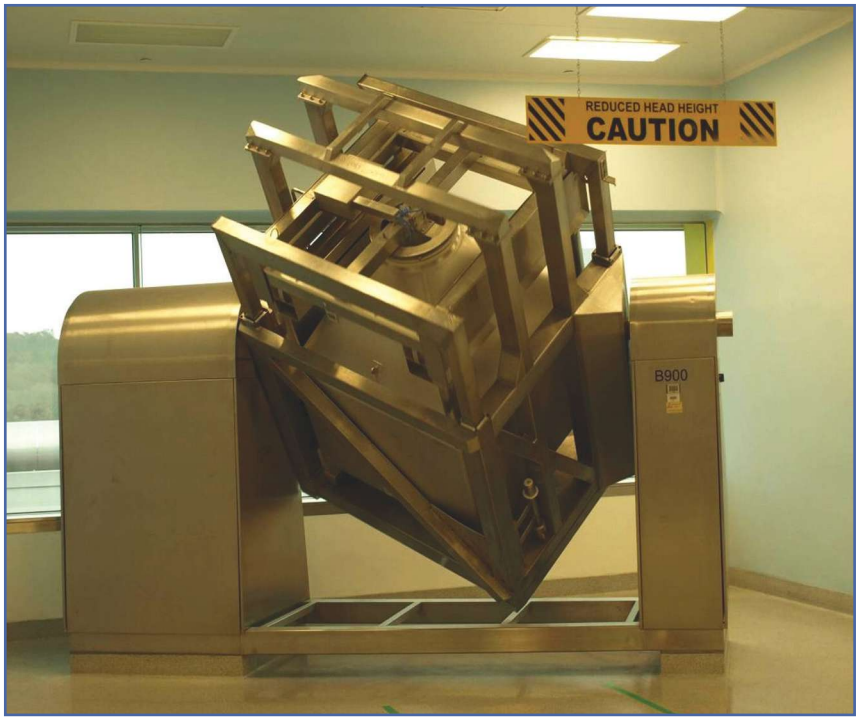

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Supply Chain Innovation Comes Full Circle

By Wayne Koberstein, executive editor

Do you have a good mental picture of the life sciences supply chain? Such a common term, widely repeated without reservation — no wonder few people stop and think before they say it. A universal principle may apply: the more used, the less understood the term.

It would be the most natural thing in the world if no one working in the supply chain could envision it in totality. At one end are specialized functions such as compound formulation and analysis; at the other, mass production and distribution. In between lies a complex line of discreet goods and services that all do their part to move products to the market. At any given point, peoples' awareness may extend a few links back or forward but never encompass a detailed knowledge of the entire chain. Why should it? Perhaps, because the knowledge is becoming valuable.

Suddenly, it seems, CEOs are discovering the virtues of quality and efficiency in the supply chain, issues they once routinely left to their engineers and heads of manufacturing. The cause goes by various names: lack of therapeutic innovation, poor R&D productivity, and patent loss, to name a few. The chief executives' newfound concern for supply issues reflects a corporate-level realization that such issues, however mundane they once may have seemed, carry strategic weight.

From a long-term perspective — and if you've lived long enough you can't ignore it — the change has been dramatic but not linear. In fact, it more resembles a circle. There were days when every pharma company was a little world unto itself, typically dedicated to a narrow product line and with administration, science, and factory buildings all on a single, walkable campus, following the old European model. Some chief execs would take me on personal tours through the plant floor, proudly pointing out new automated packaging lines with in-line QCs such as close-in video monitoring of pills and vials. But when most companies merged into global conglomerates with diverse product portfolios, the close connection of corporate management to its supply chains dissipated.

Several key phenomena have encouraged the contemporary return to supply-chain consciousness by top execs — biotechnology, drug delivery, and generics. Biotech companies revived the campus model, keeping production and supply proximate to management, and the first fundamental goal of biotech was creating new ways of producing medicines. Drug delivery and its near cousin specialty pharma also demand an emphasis on manufacturing and supply. And, perhaps also in related fashion, generics are competing ever more on the basis of quality, pedigree, and supply chain efficiency.

The growth in the use of CMOs has also fueled a return to supply chain issues for top pharma-company management. Shared regulatory accountability necessitates collaboration between sponsors and contractors. Because this collaboration is spreading, if you want to produce the best possible results at the end of the chain, you must get every link to add strength to every other. My perception is that demand will grow for people who can combine intimate knowledge of each link with an integrated understanding of the entire chain.

In a still broader context, chief executives' current concern for the supply chain stems from a shift toward premarket preoccupations. Don DeGolyer, CEO of Sandoz US, says his purview is now 60% precommercial, 30% commercial, and 10% political. (See "Rediscovering Generics — Sandoz Vows To Serve Patients First," September 2012.) That is as it should be for every exec, small-company, large-company, or any company. Innovation is a universe of breakthroughs, from the moment of discovery to each moment of translation, right on through to application in the real world of medicine.

TURNING AWARENESS INTO ACTION

Supply chain competency might make a logical benchmark for innovation — that is, if there were a critical mass of highly supply chain competent companies to form the benchmark. Yet, all the signs

I see point to an industry awakening, not to a reconstruction. Except in the aforementioned areas where manufacturing and supply are competitive essentials, the great big old pharmaceutical industry still plows along technologically, well behind many other industries with comparable supply chains.

Now, almost a decade since the FDA issued calls for QbD (quality by design), PAT (process analytical technology), and other upgrades — with a major goal, I should say, of easing the industry's regulatory burden — you will find only a few examples of companies responding materially. Even among the few such applications out there, most are small pilots or experiments that seem insignificant in the context of a Big Pharma organization. Where some alternative production platforms, such as single-use systems, have seen greater adoption, the emphasis has been on flexibility, small-batch processing, and other exceptional settings. In-line monitoring, a big advancement when I first saw it in the eighties, may still be the most popular upgrade because companies can easily adapt them to legacy systems, thus having their cake and eating it, too. Or so it seems. Companies may be, in fact, significantly under-exploiting the potential of in-line monitoring when applied in wholly new platforms such as continuous flow processing.

There is no shortage of explanations for the glacial progress of supply chain reforms in the industry; they range from defensive or apologist to cynical or resigned. Reluctance to invest, fear of organizational disruption, an "it-ain't-broke-so-don't-fix-it" mentality, and so on — all pretty much boiling down to, "We're comfortable with what we have, and nothing else has made us uncomfortable enough to change it."

Again, a circle, not a straight line, shapes progress. Companies will be reminded again and again that inefficiency and lack of "modernization" as the standard evolves cannot continue forever — or even much longer. Action must follow awareness, and executives must follow through, even at the displeasure of those down the line who favor the status quo.

The industry cannot go on criticizing regulators for imposing burdens if it is unwilling or unable to implement changes meant to lift those burdens. In other areas, industry may have a legitimate beef with regulatory overkill, but manufacturing and supply — what we know as the supply chain — offers an opportunity for companies to step up to the plate. And not only companies, but also every player who represents a vital link in the chain must answer the clarion call.

The Shifting Geography Of Life Sciences Innovation

By Richard McBlaine and Bob Bovee

The life sciences industry is experiencing change at a pace that is forcing companies to examine how they should operate and innovate more effectively. For many, the solution may involve a change of scenery. Increasingly, life sciences companies in North America are investing in locations that help contain costs while boosting access to innovation.

Facing the patent cliff and the intense price competition that comes with it, life sciences companies foresee an industry-wide loss of revenue to the tune of $110 billion or more between 2012 and 2016, according to Accenture's 2012 report, "Beyond the Patent Cliff – Sign of Recovery in Biopharma's New Normal." Recognizing that the traditional product development model no longer ensures success, companies have turned to mergers and acquisitions, licensing, and other business strategies to keep their pipelines full and to mitigate risk.

Life sciences companies don't need to be reminded that continuous innovation is central to their success. Innovation requires the ability to attract top talent and great academic partners and to build modern, up-to-date facilities. Concurrently, companies need to find more cost-effective ways to operate without diminishing the quality of their processes or products.

One way companies are aiming to meet both goals — innovation and cost containment — is by reshuffling and right-sizing their North American facilities. After the cost of new drug development, facility and real estate costs are among life sciences companies' highest expenses.

Real estate is also important when it comes to reprioritizing. As M&A activity results in excess or duplicative facilities in established clusters, companies are concurrently motivated to expand into lower-cost metropolitan areas.

A MOVE TOWARD SMALLER CITIES

In its most recent Global Life Sciences Cluster Report, Jones Lang LaSalle reveals that in the United States, life sciences companies are shifting more operations than ever before to cities where occupancy and workforce costs may be lower and where academic communities can offer fresh perspectives that may lead to a big payday down the road. As a result, smaller metropolitan areas with good academic and workforce characteristics are gaining influence in the life sciences community.

The Jones Lang LaSalle Life Sciences Global Cluster Report ranks global life sciences clusters according to weighted scores for total employment in high-tech research and hospital/medical fields, life sciences establishments, NIH funding, and venture capital funding. The top 10 U.S. clusters list represents "established clusters." The report also covers emerging clusters including Chicago, Denver, Atlanta, central/southern Florida, and Indianapolis. New emerging clusters added to the 21-city ranking since the 2011 report include Westchester/New Haven, OH; Salt Lake City; Dallas/Fort Worth; Wisconsin; and Michigan.

The report's results reinforce three key trends in life sciences business growth:

1. Smaller metro areas are gaining influence from larger markets. Boston remains the clear worldwide leader for life sciences business, but the rising stars over the past year have been San Diego, Raleigh-Durham, and Philadelphia, all of which moved into the top five rankings for the first time. Larger cities such as New York, Los Angeles, Chicago, and San Francisco remain important centers but have not kept pace with the smaller cities in the same regions.

This trend can be seen further down the list as well. Minneapolis-St. Paul, Denver, central/southern Florida, and Indianapolis all saw gains in life sciences business and are in contention for companies with expansion plans. Lower occupancy costs are one factor in attracting companies to Minneapolis instead of Chicago, or to Philadelphia over nearby New York, for example.

2. Proximity to innovation is more

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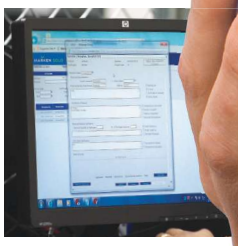


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TOP U.S. MARKETS FOR LIFE SCIENCES BUSINESS GROWTH

RANK	2012 CLUSTER REPORT (CURRENT)	2011 CLUSTER REPORT (FIRST ANNUAL)
1	GREATER BOSTON (NO CHANGE)	GREATER BOSTON
2	SAN DIEGO (+5)	NEW JERSEY / NEW YORK CITY
3	SAN FRANCISCO BAY AREA (NO CHANGE)	SAN FRANCISCO BAY AREA
4	RALEIGH-DURHAM (+5)	LOS ANGELES / ORANGE COUNTY
5	PHILADELPHIA (+1)	WASHINGTON, D.C. METRO AREA
6	WASHINGTON, D.C. METRO AREA (-1)	PHILADELPHIA
7	NEW JERSEY / NEW YORK CITY (-5)	SAN DIEGO
8	LOS ANGELES / ORANGE COUNTY (-4)	MINNEAPOLIS-ST. PAUL
9	MINNEAPOLIS-ST. PAUL (-1)	RALEIGH-DURHAM
10	SEATTLE (NO CHANGE)	SEATTLE

important than ever.

Although the industry increasingly looks to emerging markets globally for growth opportunities, much of the core R&D work will remain in the United States. It is also apparent that life sciences companies are becoming more strategic in their site selection, choosing locations with rich industry resources, investment capital, and human talent, all of which add up to a higher propensity for discovery and innovation.

The mature clusters in the United States and Europe continue to be reliable choices, with deep and well-developed resources. But smaller markets in the United States and Canada are working feverishly to bolster their industry infrastructure.

3. Economic development efforts and public-private partnerships are increasing. Recognizing that the life sciences sector has a bright future for U.S. job growth, city and state governments are positioning themselves to capture their share of that growth.

Clusters such as Westchester/New Haven, central and south Florida, Indianapolis, and Montreal offer targeted incentive packages and new state-of-the-art incubator centers and parks designed to serve the sector. Beyond incentives, clusters highlight the quality of their research institutions with government-instituted regulations and protections.

THE GLOBAL INNOVATION STAGE

Canadian markets are trending similarly to emerging clusters in the United States as cities like Montreal and Toronto offer solutions and incentives competitive with those in up-and-coming U.S. markets.

And in Latin America, clusters are acting quickly to meet the demands of local populations with increasing wealth and access to healthcare. As the demand for drugs and medical care increases, manufacturing operations in Latin America are beginning to produce not only for North American customers, but also for domestic populations.

At the global level, emerging clusters in China, Brazil, India, and Singapore have reported recent funding opportunities dedicated to the life sciences industry. Nearly all of these markets have reported increased spending on overall public healthcare as well. Although many aim to ramp up the innovation potential of homegrown start-ups, multinational companies also have an opportunity to capitalize on these offerings. Despite the increase in global competition, however, there is little doubt that core research and development will continue to take place in North American clusters.

As life sciences organizations enter this new market phase, the ability to execute on facilities and real estate strategies takes on greater importance. Success often lies in choosing the right locations, assembling the best possible incentive packages, or divesting excess properties after an M&A deal. Understanding the characteristics of life sciences property markets is an important step in these times of transition.

About the Authors


Bovee

Richard McBlaine, international director, and Bob Bovee, accounts director, help lead the life sciences team at Jones Lang LaSalle, the global professional services and investment management firm offering specialized real estate services to owners, occupiers, and investors in real estate.


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Do You Have An Exit Strategy?

By Robert Biggs and Jacob Guzman

An entrepreneur invests years, if not decades, of selfless dedication and hard work into their business in hopes of creating significant value for themselves and for investors. However, once it comes time to plan for an exit, we have found that entrepreneurs and executives are often unfamiliar with the complexities of the process and the meticulous preparation necessary for a successful outcome.

You will begin to think of an exit strategy and time frame as your life sciences company grows and develops. However, as most successful entrepreneurs can attest, the path to an exit is seldom straight, and the ideal strategy can be both fluid and elusive. Given the variability of the outcome, it is important to prepare and execute a personal plan as early as possible in order to maximize the exit's value. The most bittersweet call that we can receive from a client is the one that says, "I sold my company; let's start implementing all of the planning that we have been discussing for the last several years." While every situation is different, our hope is to provide a road map — using best practices — as you begin to think through an exit strategy and position yourself and your business for a successful outcome.

WHERE TO START?

Many people will tell you about the importance of surrounding yourself with good people, which seems clichéd. But what type of people? At the very least, your team ought to include a financial advisor, an estate planning attorney, an accountant, an investment banker, and a corporate attorney. Each of your advisors should have an understanding of your industry and your business to ensure that you receive the best-informed advice. Surround yourself with specialists, not generalists.

For example, when we met Matt Rhodes-Kropf, he was working as CFO for Avid Radiopharmaceuticals. Morgan Stanley eventually helped sell Avid to Eli Lilly in the fall of 2010. "Surrounding yourself with a team of trusted advisors as early as possible can be helpful in alleviating many of the issues that arise as a deal approaches," says Rhodes-Kropf, currently professor of venture capital at Harvard Business School. Think of this as assembling your personal board of directors. You can draw on their expertise, while you focus on maximizing the value of your business. As a deal approaches, you need your team to proactively collaborate on your behalf, rather than simply respond to your requests.

While each advisor serves a distinct purpose, open communication amongst your advisors is a key element for success. As your deal approaches, there are a number of important decisions that can impact its long-term success, both for you and the company. Proper planning will help you maximize value for yourself as well as for shareholders.

It is important to remember that while all investors have the ultimate goal of maximizing the value of their investment, there are other objectives that may come into play as well. If you have multiple investors, take the time to understand all of your investors' goals from the beginning. When you run a venture-backed business, exit strategy and timing can be complicated by factors beyond your control, so it is even more important to speak with your company's board early and often to understand its goals and desires for the business. While there are a number of different exit paths, it is best to learn about these differences early on and to do whatever it takes to align your strategy with your investors' goals. "We believe that discussing a company's exit strategy with management, existing investors, and new investors is an essential step prior to ensuring that all parties are properly aligned," says Scott Weiner, transactional partner at Pappas Ventures, a Durham, NC-based life sciences venture capital firm. Morgan Stanley recently helped take TESARO, an oncology-focused biopharmaceutical company and Pappas Ventures investment, through an initial public offering.

Sometimes, an investor will choose to be passive or want to sell its investment earlier. This situation presents an

opportunity for other investors to buy out the noncommitted investor, simplifying the management structure and ensuring that everyone moving forward is committed and unified. Once everyone is committed, it is time to form the company that buyers can see themselves owning. A business should be built to be acquired, not to be sold.

AN EXIT ON THE HORIZON

Our experience shows that entrepreneurs can be reluctant to think about an exit two to three years in advance. However, this is exactly the point at which you can leverage some of the best strategies as they relate to taxes and your estate. It is important to review asset titling and ownership as well as your current wealth management and estate plans at that time. A full understanding of liability issues and the treatment of assets in a lawsuit or upon death may help to uncover problems that need to be addressed when updating your financial and estate plans.

When you run a venture-backed business, exit strategy and timing can be complicated by factors beyond your control.

Additionally, in light of the possible upcoming liquidity event, the structure of ownership itself may need to be reviewed. Trying to update and review your wealth management and estate strategies during business negotiations is particularly difficult, due to the focus and commitment required by the management of the deal itself. Take the time now to figure out how much money you require to attain your retirement lifestyle goals. Forethought will help reduce stress, increase investor commitment, and guide the negotiation process. Now is your best opportunity to coordinate with your financial advisor and estate attorney to determine what strategies make sense for you and to implement them. "Our research shows many entrepreneurs are typically not proactive in this area until

the second or third venture, and often regrettably so," remarks Joseph Romano, executive director, wealth planning specialist and strategic partner to the CES Group at Morgan Stanley. Remember that many strategies require significant time to be effective in protecting and transferring wealth (i.e. establishing trusts, LLCs, and leveraging discounts on gifts).

"When you are within two years of a potential exit, it is essential you continue to execute your strategic plan so that buyers can envision taking over easily and smoothly," says Fahd Riaz, Philadelphia-based partner in the Business and Finance Practice and member of the Life Sciences Transactions Practice at Morgan, Lewis & Bockius, LLP. Engaging an investment banker early in the process allows investors to evaluate multiple exit strategies through a "strategic alternatives analysis." More often than not, venture-backed businesses take a dual-track approach by preparing their companies for either an acquisition or an initial public offering. Keeping your options open may help to attract a larger pool of potential buyers and/or investors, which will help to maximize shareholder value. An investment banking group that knows your industry and focuses on transactions within your expected deal size can be helpful in identifying buyers and can help position your company for its ideal exit. Use the specialists you hire to help familiarize your executive team with the process, negotiation points, and priorities.

As you prepare to formally begin negotiations, it is essential that your team understands the need to maintain confidentiality and focus on the task at hand. Personally, this is one of your last opportunities to complete any gifting/transfer strategies, as well as to create a list of the things you need to do in order to stay focused. Be sure you fully understand your key negotiation points and expectations for a deal. Life will quickly become busy and hectic, and this time of calm, when you have a team of trusted advisors working on your behalf, will truly pay dividends. Lean heavily on your advisors and be sure that you delegate work appropriately in order to make effective use of their expertise.

LIFE AFTER AN EXIT

Once your deal is announced, you will be overwhelmed by "new friends" and people wanting to help you with your newfound wealth. It is important to remember that there is no rush. Your financial advisor will assist you in developing short-term investment strategies which will allow you time to relax, reevaluate your goals, and plan properly before you jump into new investment strategies. Despite what you will hear from a variety of sources, there is no such thing as a "too-good-to-pass-up" investment.

Once you have had the opportunity to recover, it is important to revisit your comprehensive wealth management strategy to assure that it remains in line with your family's long-term goals. By incorporating your accountant, estate attorney, and wealth advisors, you can put together a plan that best suits your future needs. Some key areas to consider as you look ahead are tax, estate, and wealth protection planning.

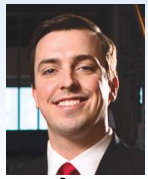
As you prepare to formally begin negotiations, it is essential that your team understands the need to maintain confidentiality.

Guiding a company up to and through an exit can be overwhelming. It is essential that entrepreneurs surround themselves with a strong team of advisors who are specialists in their respective fields. By delegating early and effectively, entrepreneurs can focus on what is most important: driving value for themselves and their investors. By preparing a personal plan early, and updating it often, entrepreneurs can maximize value through hard work, focus, and dedication, creating the best possible outcome for all parties involved.

About the Authors


Guzman

Robert Biggs and Jacob Guzman are financial advisors and corporate client group directors at Morgan Stanley. Both are founding partners of the CES Group which focuses on providing corporate and executive services for entrepreneurs and senior executives.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Regulatory Science Unlocks Therapeutic Innovation Worldwide

By Wayne Koberstein, executive editor

Dr. Ling Su, a leading industry scientist and current head of the DIA, describes how emerging markets such as China are working with developed nations to eliminate regulatory roadblocks in clinical trials.

Dr. Ling Su looks back on a long career in drug development with big companies like Novartis — and on his past year as board president of the Drug Information Association (DIA). At the same time, he looks forward to his new role on the front line of regulatory science in China, where he is strategic adviser at Sidley Austin's China life sciences practice and volunteers his expert support to the China Food and Drug Administration (CFDA). I recently spoke with Dr. Su by phone, between his office in Shanghai and my location on the U.S. West Coast, 15 hours apart. Clinical development folks in companies conducting global trials can likely identify with the situation: When communicating halfway around the world, they know it's best to ignore extraneous factors like time zones and focus only on the essentials of the conversation.

As it happens, a similar principle applies to how the world's regulatory authorities may build better pathways for global product development in the life sciences industry: Cut away the undergrowth and overgrowth of local barriers, and plot a route that follows the growing scientific consensus on essential criteria for evaluating and regulating new therapies. Authorities who wish to join the leading regulatory peers, attract global trials, and stimulate therapeutic innovation have already taken a turn toward common goals — and are finding ways to do so without sacrificing their cultural imperatives, according to Su.

SCIENCE BEFORE REGULATION

Although governments have long regulated science, the idea that science should take a firmer hand in guiding regulation seems to have dawned late. Scientific principles can replace bureaucratic expediency to optimize data gathering and analysis. Rational and empirically derived methods can exorcise inefficiencies, standardize formats, and integrate varying data needs in global or multiregional trials. National health authorities can take a scientific path toward adopting common protocols and end points where they can and predictable variations where they cannot. Regulatory innovation can unleash medical innovation. It can all happen, says Su, but only if industry and regulators work on it all together, upon the common ground of regulatory science.

The DIA is an important international platform on that ground. Without the global forums maintained by DIA and other organizations such as the American Association of Pharmaceutical Scientists (AAPS) and the U.S. Pharmacopeia (USP), the regulatory science movement might remain a Tower of Babel, forever divided not only by discipline but also by region and nation. The DIA has always brought together regulatory professionals, scientists, and others on both the industry and government sides through its educational meetings and services. But its traditional reach was mainly confined to North America and to drug development. On Su's watch, the association has grown in parallel to industry and market trends — becoming more global, more connected, and more diversified in scope beyond drugs to biologics, devices, and other medical products. It is now a key mediator of globalization in the regulatory realm, increasingly focused on addressing the built-in barriers to life sciences innovation, inside and among the world's leading health authorities.

And "leading" does not always mean "big." Emerging markets and the nations they represent are huge in potential, but still relatively tiny in their regulatory infrastructures. Their global influence thus far outweighs their current status of development. How the fledgling health authorities take shape as they grow, mature, and interact with the outside world will largely determine the outcome of efforts to rationalize medical-product development on a worldwide scale. China, India, and Latin America are the most dramatic examples of rapid regulatory evolution in emerging markets, which is why they have seen a major expansion of DIA activities during Su's tenure.

"We need to continue to bring the strength of the DIA to the emerging regions," Su says. "The benefits are twofold: One, we can use what we already do best — be a neutral platform for information and knowledge exchange among regulators, industry, patients, and others

in these regions; and two, because those regions are very different from the U.S. and Europe, there is a need for international dialogue that also facilitates the DIA's growth and development there."

Widening the DIA's product focus also makes sense in light of current trends, despite the prominent use of "drug" in the group's name. Few medical products now exist in pure isolation; biologics, personalized medicines, companion diagnostics, delivery advances, new drug/device combinations — all are evidence of how development and regulation of various product types can overlap. "We are looking to develop activities to extend into the other product areas," says Su. "But our new efforts have to be consistent with the quality of our traditional programs, and we must work with other organizations where they are doing things better, to collaborate with them in expanding our competent areas."

OPENING THE GATES TO INNOVATION

The overall broadening of the DIA's focus mirrors the evolution of regulatory systems, Su explains — and he says both serve the same goal: innovation. Regulatory science incorporates a wider

SCIENCE, INDUSTRY, & REGULATION — THE VIEW FROM ALL SIDES

Dr. Ling Su brings a scientist's perspective to the regulatory field. Pharmacoepidemiology was an early interest, and he still teaches related university courses at Fudan University. After earning his B.S. at Shanghai Medical University, he added an M.S. in clinical pharmacy and drug development and a Ph.D. in epidemiology at the University of North Carolina at Chapel Hill. He saw service at The Bureau of Drugs of the Ministry of Health in China and in the FDA's CDER; then he joined industry, eventually working in regulatory and drug development positions at MSD, Roche, Wyeth, and Novartis. While still at Wyeth, he joined the DIA board and was elected into the volunteer office of president of the DIA board in 2011. His presidency ends in July 2013. His current job at Sidley Austin places him right at the intersection of China's small but rapidly modernizing regulatory agency and of life sciences companies of all sizes, types, and national origins seeking market entrance to China.

awareness of factors that determine therapeutic response and outcomes. Thus, the science envisions a new framework for evaluating new treatment candidates and one that is applicable in industry, regulation, and medical care. The framework takes into account not only intrinsic factors such as drug metabolism, but also the extrinsic factors — medical practices, disease definitions, standard-of-care, and even regulatory requirements — that affect how the therapy is used and response monitored in development.

"Extrinsic factors become more and more important, but they are much less understood," Su says. "You look at metabolism, at the enzymes, and the metabolic pathway, and you get data everyone understands. But the larger context of medical practices — how patients use the product, how the disease is defined, and the risk factors in certain populations — are much less understood, and they pose much bigger issues when we look at the data."

Until recent years, China and other countries clung to the metabolic focus as the EU and the U.S. moved toward a greater inclusion of extrinsic factors. China, Japan, and South Korea decided to investigate potential differences in drug metabolism between their populations and "Caucasians," while Western authorities encouraged developers to gather more and more extrinsic clinical data. Now, however, the various agencies have converged considerably, according to Su.

"This is a great example of how regulatory science has evolved with the rise of globalization. If you see how the FDA, the EMA (European Medicines Agency), Japan's MHLW (Ministry of Health, Labor and Welfare), and the CFDA evaluate data from other countries, they have more or less come to a common understanding whether or not the data may be applicable to their respective populations."

Su takes proclamations by FDA Commissioner Margaret Hamburg and other agency heads as serious evidence of their commitment to giving developers wider latitude in data points and evaluation. More latitude means more flexibility in designing clinical trials for novel products and combinations for a global market. He sees the shift as a basic change in mission and identity. "Regulators need to be not just gatekeepers but gate-openers — to work with the industry and the academic community to promote innovation and to move ahead with the new ways that products will be developed and evaluated."

INDUSTRY & REGULATORS MUST WALK TOGETHER

Collaboration in regulatory science is taking several forms: among agencies, between agencies and industry, and among companies in the industry. Of course, regulatory science cannot cure all innovation-impeding ills. It cannot, in itself, raise Big Pharma's poor R&D productivity, pump more money into novel research, ensure reimbursement, or fund the next Genentech. But to the extent that regulatory science eases the regulatory burden for developers, it will remove a widely acknowledged major impediment to innovation.

Still, in Su's view, it is a burden that neither the agencies nor industry can remove alone. Whether

CHINA AS A HARBINGER OF REGULATORY CHANGE

As president of the DIA board, Dr. Ling Su views the entire regulatory world at once. But as his career focuses increasingly on China, where is he now senior advisor to Sidley Austin's China life sciences practice, he sees the application of regulatory science in its most fundamental mode — guiding a young agency, China Food and Drug Administration (CFDA), through critical steps in its evolution. Su speaks about the unique challenges and wider context of the CFDA's evolutionary development.

"There is a critical connection between innovation and regulatory science that has characterized the regulatory landscape in China. Regulators here once had the mission of promoting public health; that is, to protect. They could say, 'yes, a treatment will work,' but they had no official interest in facilitating introduction of innovative products.

"CFDA is really different from the FDA and other agencies. It started rather late with regulations, so it is under a lot of pressure to cope with domestic issues such as generic drugs and also to deal with innovation. All the major companies that have business in China and a lot of the innovation works through Big Pharma or small start-up companies. They are very active. So the regulators have to deal with both sides, and it is pretty challenging for the agency by itself. The CFDA is very small and understaffed; there are only about 200 people here. Their responsibility also includes food, cosmetics, biologics, pharma, medical devices, and other health products. So in resources, experience, and expertise, it is nowhere near the FDA and EMA (European Medicines Agency). We do see improvements in the CFDA, especially in technical degrees, and it is moving toward more transparency and also toward more science-based review. It will take time for the agency to develop, and we — industry, academia, society, etc. — need to support it. The CFDA still has a long way to go to become a global regulatory agency, but it is taking the right actions.

"China is putting out a lot of effort to promote innovation for its own market. The CFDA has helped innovative companies a lot, guiding them in creating a product-development plan, holding advisory meetings, and so on. It has also started similar meetings and mechanisms to support innovative companies, including foreign companies doing business in China, in developing their products. That's a good sign, but there are a lot of issues to solve, particularly on the resources side, and also experience. We need to become more competent and proactive."

to reform whole systems or avoid hurdles in a particular trial, companies and regulators must share the heavy lifting, he says.

"When a clinical trial is globalized, we have to think about how to deal with the data coming from all the countries involved. It is too late if you wait until the data comes in and then say, 'oh, there's a problem in the scientific, GCP, or regulatory area.' So regulators and companies need to work together, even before the trial starts, for globalization to show its benefit."

The FDA's Critical Path Initiative proposed greater regulator/academia collaboration to develop new solutions, such as the use of biomarkers in clinical trials. In 2010, MIT, the EMEA (European Medicines Evaluation Agency), and other parties convened a project called NEWDIGS (NEW Drug Development ParaDIGmS), working with the FDA and other agencies "to conceptualize and validate new policy frameworks, technologies, and development processes" in "key areas with potential to transform the healthcare innovation system."

Companies have also banded with each other to improve the R&D process. In 2012, 10 top pharmaceutical companies launched the consortium TransCelerate "to identify and solve common drug development challenges with the end goals of improving the quality of clinical studies and bringing new medicines to patients faster."

But in spite of such initiatives, Su says something is seriously missing. "I don't see a lot of projects addressing the overarching issue — industry and the regulatory agencies working together to build a comprehensive model of what drug development should look like." To some, the current lack of such collaboration is a huge failure, but to experienced optimists like Su, it is a grand opportunity.

4 Questions For An Oncology Big Pharma CSO

1. Is there a particular strategy/process that you follow regarding the types of compounds you pursue or which therapeutics to focus on?

Our approach to developing the next generation of cancer therapeutics is based upon specific areas of biology where the company has developed internal strength. These areas include hormonal agents and their receptors, the ubiquitin and ubiquitin-like pathways regulating protein homeostasis, and cellular metabolism. The pursuit of unique drug targets in these key areas of science coupled with a balanced set of targets in signal transduction pathways represent the principal components believed necessary for building a strong and diverse pipeline of future drugs. An additional emerging area of interest is in the application of targeted antibody drug conjugates (ADCs), which offer specificity and the potential for diverse chemical payloads.

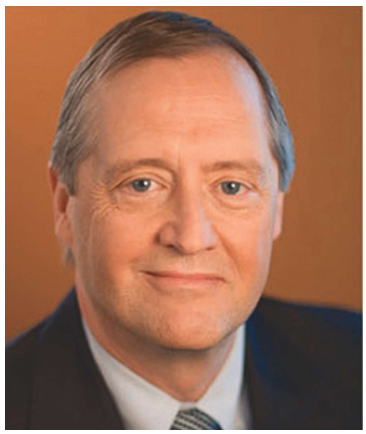
The overarching imperatives guiding the research vision begin with an understanding of unmet medical needs within the changing competitive landscape and commercial environment. The research strategy then focuses on disease pathways and drug-target classes where the research organization has knowledge, experience, and prioritization of resources for foundational areas of scientific and commercial leadership.

2. Has that strategy/process changed in recent years or at least since the Millennium acquisition?

The fundamental strategy has not changed since the Millennium acquisition. However, the range of biology expertise areas was expanded through the existing Takeda oncology research organizations in Japan and in California. The global oncology marketing strategy and market preparation teams are led by Millennium with participation from all regions. Plus, we are constantly engaged in exchanging employees on both sides to help offer an indigenous perspective in key functional areas.

3. In general, has the pharma industry increased its focus on cancer-related drugs in recent years? If so, why?

One consequence of more people living longer is that age-related disease classes such as cancer and neurodegenerative diseases become more prevalent. Takeda's decision to focus on this therapeutic area is, therefore, based on the strong growth projections for the global oncology market driven by continued unmet medical need. We are driven by an increasing demand for these medicines to treat those unmet needs within various forms of cancer and are influenced by rising healthcare spending in developing countries like China and Russia and within areas of South America. Plus, a global expansion of the world's middle class, most of whom have increased access to better and more sophisticated healthcare in other emerging markets — a key focus for Takeda — will continue to stimulate interest and growth for cancer medicines. Many of the new cancer drugs recently approved and in development are aimed at cancers with specific genetic variations, so the drugs can be targeted to patients who are most likely to benefit, which certainly has the potential to impact their cost.



Dr. Joe Bolen

Bolen is CSO at Millennium: The Takeda Oncology Company. He has extensive research and management experience within the life sciences industry and in particular oncology R&D.

4. How do you make the big decisions? For instance, how do you know which drugs to pursue?

At Millennium, our goal is to transform cancer therapy from tissue histology-based diagnosis and empirical treatment course to molecular genetics-based diagnosis and long-term treatment options. Our R&D is driven by biology and biomarker discovery while focusing on pathways of combination therapies based on individual patient profiles of an evolving disease.

This activity requires characterization of a patient's current cancer in the clinic. In recent years, Millennium has focused increasingly on its evolving translational research program and the close collaboration between discovery and development. Our translational medicine department in clinical is linked to discovery and nonclinical development through ongoing research and acts as a bridge to clinical research implementation. The collaboration is maintained from early discovery through clinical proof-of-concept, and serves as a cross-functional strategy linking teams and sharing technology platforms.

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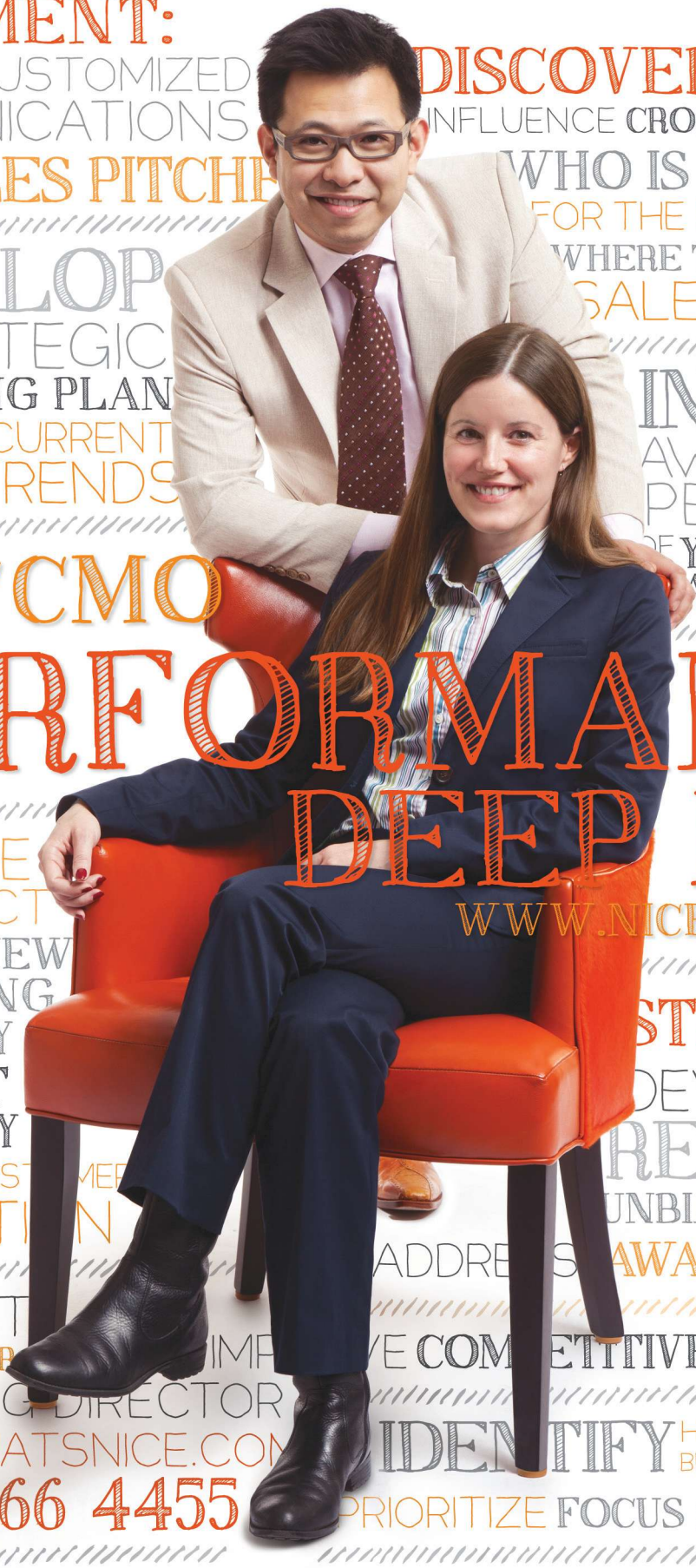

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Traveling The Road To Clinical Trial Transparency

For those of us in the business of managing clinical trials, it has been quite a journey keeping up with the requirements for clinical trial disclosures. Although the road to transparency was paved with good intentions, for many it has been a bumpy one, and we are not there yet.

From the very beginning, there have been proponents of and opponents to transparency, each representing its own interests. There is reason for these opposing views. The public is demanding information that private industry considers proprietary. Consistent pressure from the general public, healthcare professionals, journal editors, media, and legislators has brought about the passing of two laws, (1) Food and Drug Administration Modernization Act of 1997 (FDAMA), and (2) Food and Drug Administration Amendment Act of 2007 (FDAAA). Proponents of trial disclosure emphasize the importance of this information for patients and their caregivers interested in trials of investigational drugs. This is especially important when available (marketed) treatment options are very limited or no drug is available. Another argument in support of trial disclosure is the desire to share the full context of the research study results in order to prevent a "publication bias" (i.e. cherry picking). If protocol and results summary information for all studies in a given drug program are shared, this curbs "publication bias" in which only studies with positive results are published, a practice that can be especially harmful to physicians practicing evidence-based medicine. Disclosure of full-trial results may also benefit research as a whole. An organization about to conduct a trial may build on the information already available for a comparable chemical or molecular entity, trial design, or target-study population. With this in mind, researchers could learn about safety issues before putting patients at risk.

This is where the journey reaches a split in the road. The public benefits from full-trial disclosure as do researchers because they can learn from other trials and possibly spare themselves redundant testing. However, from a competitive standpoint, if you funded a clinical trial that yielded important scientific information, would you want to share these findings with those also in the race? Only 1 in 5,000 compounds in the development pipeline will make it to market, with an average cost of $1 billion. With an 8- to 10-year patent protection period you have limited time to recoup your costs, justify your spend and record a profit to shareholders, and invest in future research. For this reason you may want to prevent your competition from viewing your intellectual property.

ACCELERATING FORWARD

The wheels of change continue to turn with two new (i.e. late last year) developments that could more than double the current reporting requirements and begin fining sponsor companies that are out of compliance.

On Aug. 2, 2012, a group of House Democrats introduced the Trial and Experimental Studies Transparency (TEST) Act of 2012, legislation that would update and expand the clinical trial registry data bank ClinicalTrials.gov. TEST mandates the addition of Phase 1 studies, postings of informed consent forms and full protocol documents, disclosure of results for investigational drugs, and reporting compliance and enforcement activities to Congress. This last item identifies enforcement activities. Current U.S. law requires the registration of applicable clinical trials on a public registry and results reporting within one year of study completion for marketed products. However, an audit published in 2012 has shown that 80% of trials failed to comply with this law. Despite this fact, no fines have ever been issued for noncompliance. But that may be about to change.

In September 2012, the U.S. Department of Health & Human Services surrendered to the FDA its authority to oversee information filed to ClinicalsTrials.gov, and to seek out those who fail to file or file misleading or false data. This authority will finally give the current FDA law some teeth to enforce compliance. Potential fines of up to $10,000 per day would be a bitter pill for pharma companies to swallow.

The journey to meet current requirements has already seen many twists and turns in the road, and by all indications the next leg of the trip may be uphill. Pharma companies will need to take caution and prepare accordingly, or potentially face the long arm of the law.

Joe Archer

Archer is the associate director of data sciences and disclosure services at MMS Holdings Inc. He leads the global clinical trial disclosure teams at MMS and brings a depth of technical experience and regulatory feedback on the process.

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Be A More Effective Leader By Getting Rid Of Waste

By Eric Shaffer

To be an effective leader, it is important to weed out waste and focus on those activities that really matter. Waste is the destroyer of time, energy, and company profits. It is estimated that 95% of the time in an average working day is spent on waste.

What is waste? Waste is anything that does not add customer value, the customer is not willing to pay for, does not add to the net benefit, sits, is stored, is overproduced, or is reworked.

In essence, if there is activity that does not add net value and meet customer expectations for quality and timeliness, then it is waste.

A VP was concerned that one of his company's main products was underperforming. He had a theory it was related to the product's old marketing campaign, so he asked the marketing director to see if the campaign could be refreshed.

The director of marketing assigned a young marketing manager to work on the product campaign. Once it was completed, he reviewed the new campaign with the director. The director asked the manager if he had done research to understand the campaign's expected effectiveness and if there was a means of measurement.

The director was disappointed to find out the manager did not completely investigate the potential effectiveness of the campaign and there were no plans to measure the results. The director asked the manager to reassess the campaign and develop a measurement system, as launching the campaign to an entire sales force could potentially be a waste of the time for the company, sales reps, and customers.

Waste is like throwing a pebble in a pond. The splash may be small, but it has a ripple effect that spreads across the entire pond.

Simple Ways To Identify Waste

1. Does the activity meet a customer requirement? If your customer was on the conference call, in the meeting room, or on the manufacturing floor with you, would they want to pay for the meeting, activity, or procedure? If you answer no to these questions, or you have to take time to justify why the activity would meet customer needs, then it is probably waste.

2. Does the activity add value? Does it make your company money? Does it increase the net value of your company? If your answers are all no, then it is probably waste.

3. Do you have a lot of paperwork or emails sitting on your desk or in your inbox? What would happen if they did not get acted upon? If they have no connection to company income or customer needs, then they are waste.

Waste is a revenue killer and customer turnoff. Eliminate what the customer does not want and does not want to pay for, and focus on the revenue-generating activities.

For more than 16 years, Eric Shaffer has been successfully leading and developing the next generation of leaders in business, sales, and healthcare. He is a magna cum laude business graduate and certified Lean Six Sigma Black Belt. He champions the idea that great leaders value their people and their clients. Years of accolades from colleagues, employees, and clients attest to his commitment to produce lasting high performance.

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