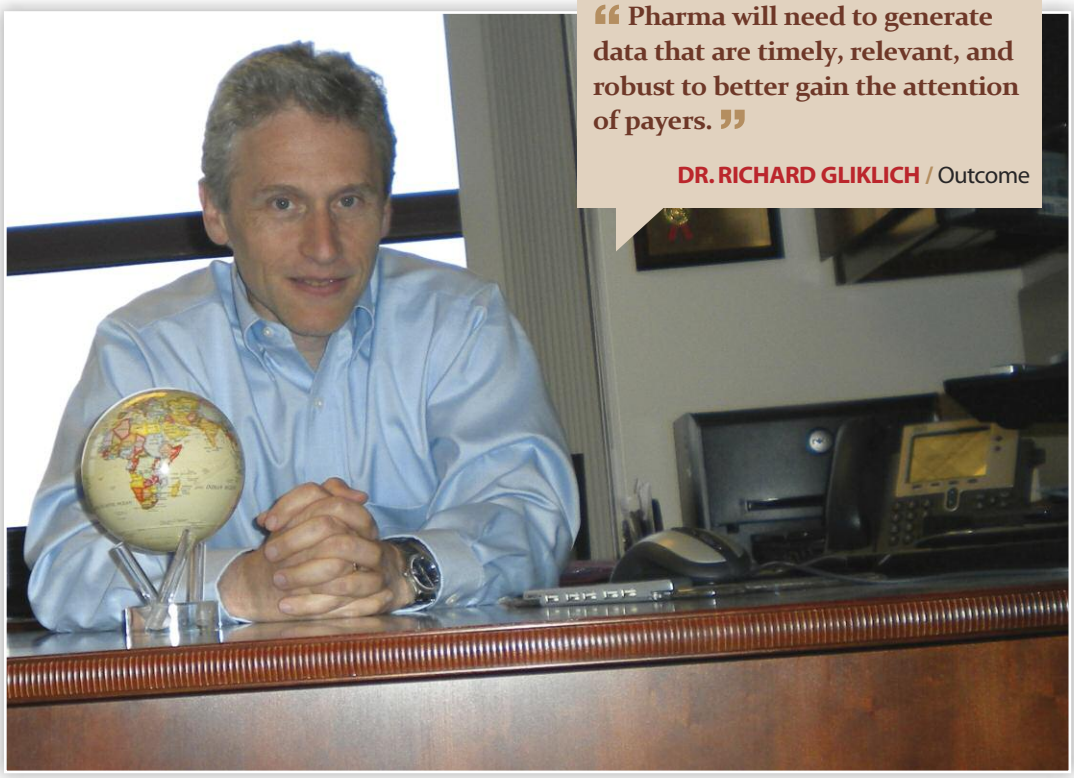
Taren Grom

New Ways FORWARD

Experts agree the time has come to re-evaluate the overall working culture of the life-sciences industry, and they say innovation, new payer models, new stakeholders, and new outcomes are key considerations for future success.



> **"Pharma will need to generate data that are timely, relevant, and robust to better gain the attention of payers."**
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> **DR. RICHARD GLIKLICH** / Outcome

According to Carolyn Buck Luce, global pharmaceutical sector leader at Ernst & Young, pharma companies have historically innovated from the "inside-out" as opposed to the "outside-in" and their cultures and operations have been relatively insulated from the forces that have disrupted other industries.

"Information has been highly protected and the regulatory environment has chilled interactive conversations with outside stakeholders," she says. "That mindset has led to a culture of internal silos and sharing on a need-to-know-only basis. Companies need to invest in building a learning and knowledge-thirsty environment as a prerequisite to a culture of innovation."

Joan Bachenheimer, co-founding principal, BBK Worldwide, contends that in 2012 the biggest challenge the life-sciences industry will face is its ability to achieve the efficiencies and profitability shareholders have come to expect while meeting healthcare consumer and payer standards for health outcomes performance.

"This is no longer just a requirement for the biggest companies as they negotiate with government health schemes across the globe," she says. "For those of us who service biopharmaceutical and medical device companies — particularly within the clinical research sector — we must ensure that our business objectives are aligned with public health requirements, including the use of increasingly limited financial and healthcare provider resources."

David Ormesher, CEO, closerlook inc., quoting from business guru Michael Porter and his disciples, says a sustainable business model must be based on product innovation, low-cost supply chain, or customer intimacy.

"Companies that try to do all three utterly fail at differentiating themselves in the marketplace," he says. "The life-sciences companies that will prevail in the coming industry transformation will be led by executives who have researched their market, analyzed their core capabilities, and made choices to specialize."

Mr. Ormesher says a key building block for industry transformation is a detailed understanding of healthcare professionals.

"Although traditional market research is an important foundation, it doesn't capture insight at the level of the individual provider," he adds. "For this, pharma needs physician CRM. Cross-brand physician CRM that captures data from all personal and nonpersonal touch points is becoming a critical tool, not only for marketing and messaging decisions-but also for strategic go-to-market considerations. Is our best customer a private practice

physician with a wealthy clientele that is largely insensitive to cost? Or is it a government payer needing to drive outcomes-based value regardless of consumer or physician preferences?"

Innovation

Most industry experts agree that the need for continuous innovation is the most important factor driving the life-sciences industry today, but it's not just scientific breakthroughs that will be important but new types of strategic and nontraditional partnerships.

"Companies generally have only 11.5 years of effective patent protection," says Dave Fishman, president of Snowfish. "By 2024, virtually no significant revenue will be generated by today's approved branded products. Developing strategic partnerships is key to addressing this."

"Life-sciences companies will need to rethink the rules of engagement with their neighbors in the healthcare ecosystem," he adds. "Virtually every relationship is strained, whether with providers, consumers, payers, disease management companies, advocacy organizations, regulators, or the government. Pharmaceutical companies represent innovation and a path to increased quality of life for millions, but the industry must earn that respect every day at those moments of truth when its products are prescribed and administered and refilled and reimbursed."

Because of a shrinking drug pipeline, and other challenges and trends such as healthcare reform, the most important business objectives for life-sciences companies are to move to a more flexible cost structure across all parts of their businesses and to address innovation challenges so that they can be more adaptable to the changing landscape, says Subhro Mallik, associate VP, life sciences practice, Infosys Ltd.

"Life-sciences companies are operating in an environment that is beset with regulatory issues and is ever-changing," he says. "They will need to look at new, flexible business models that may involve outsourcing or breaking off parts of their businesses, and to technology to achieve their objectives. They will need to embrace the idea of greater collaboration with other companies, and create and leverage a larger innovation ecosystem. Pharmaceutical companies will also need to embrace a new mindset that it's okay to fail, but to fail fast, fail quickly, and hence fail cheaper."

Bringing innovative products to market today involves thinking outside the box, Mr. Fishman says.

> "In this prove-it or lose-it environment, companies will need to take steps to demonstrate the superiority of their products."
>
> **CAROLYN BUCK LUCE** / Ernst & Young

"Genomics and personalized medicine present enormous opportunity and risk," he says. "Drugs that have failed in the past due to trials that included a diverse genetic pool have the potential to be successful in a far smaller pool. It is critical to avoid potential development pitfalls and ensure that the focus is on more optimal candidates. This may be accomplished through in-depth clinical data evaluation; we term this clinical data gap analysis. With respect to increasing the number of potential product candidates, partnerships provide a strong opportunity."

Partnership Possibilities

A new report from Quintiles called New Health Report 2011 finds that the new health environment requires collaborative relations with stakeholders throughout drug development.

For many companies, partnering is a viable strategy on a number of fronts, and at its heart, a great strategic partnership is built around a strong scientific connection and a commitment to a shared vision, says Cláudia Hirawat, senior VP, corporate development, at PTC Therapeutics.

"Even more than the business and scientific case, we have seen that the success of a collaboration depends on the quality of the relationships, between companies and be-

Trending in 2012

According to Carolyn Buck Luce, Global Pharmaceutical Sector Leader at Ernst & Young, in 2012, members of the life-sciences industry will need to:

- **Be ruthlessly clear** about what pipeline choices will go forward based on a critical assessment of payers' willingness to reimburse.
- **Align strategic, operational, and capital planning** around objective drivers of value and outcomes.
- **Invest in organizational capabilities for organic and inorganic growth in emerging markets**, where all the growth will be for the foreseeable future. And this means doing business differently to be successful.
- **Undertake an in-depth look at the global talent pipeline** and succession planning based on skills necessary for a changed world transformed by data and technology and requiring radical collaboration across silos.
- **Employ capital strategies** as a driver of value in the business, and look at strategic divestitures or spinouts, out licensing, or minority investments to de-risk product and market innovation, as well as emerging market expansion.
- **Embrace the imperative** of shifting toward becoming an information-rich, outcomes-based company to build competitive advantage in a world of Pharma 3.0.
- **Shrink their footprints in the U.S and Europe**, while at the same time focusing on new strategies in emerging markets to partner with strong local players to create regional powerhouses and see the world through their eyes to co-create value.
- **Shift more resources** from the blockbuster chronic disease model, with a few exceptions like diabetes, to the micro patient orphan drug model.
- **Advance their personalized medicine strategy** by running clinical trials targeting sub-patient populations for very narrow indications, which has the dual benefits of lower costs and faster FDA approval time. Optimize the data on hand or access new data for better decision-making.
- **Collaborate with others** in clinical development — compete on the science, not on process.

SOUND BITES FROM THE FIELD

The Top Trends Impacting Corporate Strategies

WILLIAM BAIRD III is Chief Financial Officer of PTC Therapeutics Inc., a biopharmaceutical company focused on the discovery, development, and commercialization of orally administered small-molecule drugs that target post-transcriptional control processes. For more information, visit ptcbio.com.

For several years, the trend in financing emerging companies has been the virtual model. Take a single asset, create a virtual, largely outsourced team, advance the asset one or two steps along the clinical development path, and look for an exit. The challenge with this model is that it doesn't support the creation of successful, sustainable, freestanding companies. Clearly, the next Amgen, Genentech, Celgene, or Gilead will not come from this virtual funding model. In 2012 and beyond, to create an integrated company with multiple products, we need to look beyond the VC model to collaborations and non-dilutive grants to fund the pipeline.

DENISE (DEEDEE) DEMAN is Founder, Chairman, and CEO of Bench International, a global retained executive recruiting and consulting firm providing senior talent to life-sciences institutions. For more information, visit benchinternational.com.

1. There is a need to reframe the timetable of business thinking. Life-sciences companies are addicted to quarter-to-quarter results. While quarterly tracking is important for reporting and financial purposes, it doesn't and shouldn't ever define the business. Pharma must change its thinking, planning, and decision-making to reflect forecasting the business out in 10-year increments.

2. Recognizing human assets are more important than molecular assets. Molecular assets cannot be optimized if the wrong human assets are in place. A company can have all the money and technology in the world, but without the right human assets, it has nothing.

3. Eliminating meeting logorrhea. Life-sciences executives are burdened with so many meetings that it's difficult for them to do their jobs and what they're destined to do. Establishing protocols for determining if a meeting is truly necessary will have profound effects on productivity, morale, and innovation.

TERRY HISEY is Vice Chairman, U.S. Life Sciences Leader, Deloitte LLP, which provides audit, financial advisory, tax, and consulting services. For more information, visit deloitte.com.

1. Continued focus on cost. Dealing with ongoing realities of moving from vertically integrated to virtually integrated.

2. Health reform and the increasingly informed consumer will require companies to be more articulate on value proposition.

3. M&A/divestiture/licensing — all things associated with the constantly changing asset portfolio.

DR. ARIS PERSIDIS is President of Biovista, a privately held biotechnology company that finds novel uses for existing drugs and profiles their side effects using their mechanism of action. For more information, visit biovista.com.

1. Payers and society are demanding more affordable healthcare based on drugs that work. A combination of reducing the cost of development and focus on outcomes that demonstrate superiority is a major theme.

2. Emerging markets appear to be significant sources of new revenue. But for these to be realized, new payment models for the social healthcare of these markets need to be developed, and drug development itself needs to adapt to the molecular uniqueness of populations not represented in the Western world.

3. The industry is realizing that it has a very large-scale internal data source that is not understood, analyzed, or exploited fully, which may reveal further significant uses of its existing drugs, or novel biologies that may lead to effective new therapies. A major trend is to either out-license such assets or to develop new capabilities, internally or through partnerships, that will help extract these hidden gems.

LARRY RADOWSKI is Director, Regional Operations, Integrated Project Management Company Inc., a project management consulting firm specializing in the life-sciences industry. For more information, visit ipmcinc.com.

1. The growth of emerging markets. The economic growth in countries such as China, India, and Brazil is driving an increase in consumer buying power, which in turn is driving the growth of local pharma/health industries. These three nations, for example, already outpace the United States, the EU, and Japan in medical technology. As these markets continue to grow, cross-national development projects, technology transfers, regulation, and licensing activities will become far more complex, compounded by differences in cultural norms. Strong project management will become more important, to keep projects on the rails and provide a third-party bridge between players. Emerging markets also would benefit from building local pools of expertise, so they can catch up to countries with more mature processes and infrastructures.

2. A more complex and lengthy FDA process. FDA review time for drugs jumped by about 30% in 2008 compared with 2003 through 2007. Drug approvals in the EU now occur two and a half months earlier than in the U.S. — a clear reversal from the past. Further complexities around product approvals arise due in part to the FDA's shift to prioritizing oncology drugs, as well as the agency's manpower shortage. The result is that companies are having a hard time determining how to balance their portfolios. What's the right balance of candidates in the drug development pipeline? What products may be reviewed quickly, and what might lag? What will change next to alter the balance once again? Such uncertainties mean that companies will have to make very objective, analysis-driven decisions on how to stock their pipelines and re-analyze their portfolios frequently against the dynamic regulatory environment.

3. The advent of "open-access" R&D. The shift of R&D from in-house to academia marks a significant change in how pharma companies will make new medicines. The Structural Genomics Consortium, a prominent public-private research partnership, is a prime example. Open-access R&D may pave a faster, possibly less-costly road to innovation than all-internal research efforts.

4. Increased regulatory scrutiny is a burgeoning trend. Companies are struggling with how to respond to regulatory mandates without stifling work on their core business. When companies attend to an important regulatory issue, everything stops to focus on solving the problem. But companies can't afford a fire-drill reaction every time. Neither can they afford to hire a slew of additional employees. Companies will need to take a process-driven approach to keep their activities running smoothly while resolving

periodic regulatory issues. For example, audit pre-planning and readiness assessments are no longer nice-to-have initiatives; they are now necessary mitigation steps.

KEN RIBOTSKY is President and CEO of The Core Nation, a family of healthcare marketing and medical communications companies (CoreCreate, Brandkarma, and Alpha & Omega) that offers strategic, branding, and creative consulting services. For more information, visit thecorenation.com.

1. R&D costs continue to rise and will continue to negatively affect not just innovations in medicine, but the ability to bring new drug therapies to market. Fewer drugs will be able to make it completely through the approval process, and we will see more therapies being abandoned midstage in clinical development.
2. Payers are powerful stakeholders, and cost is always their bottom line. Increased cost pressures from payers will continue to expand the use of generic medicines. The cost that we will have to bear is decreased innovation and drug discovery.
3. We will see a shift of attention from drug discovery to improved health outcomes, which in the United States will be driven by the need to demonstrate a brand's true value through comparative effectiveness research.

JEAN LIM TERRA is President of the Amgen Foundation, which seeks to advance science education, improve quality of care and access for patients, and support resources that create sound communities where Amgen staff members live and work. For more information, visit amgen.com/citizenship/foundation.html.

Discovery, innovation, and progress — fueled by the simple desire to make something better and improve quality of life — are at the core of the biotechnology industry. Today's companies must approach community engagement the same way we do business — searching for the best ways to bring capabilities and resources to bear on societal and industry issues — to make impactful and sustainable contributions. We know that discovery and innovation are critical to the competitiveness and success of biotechnology companies like Amgen, our leading universities, and our nation. Yet, to truly harness the promise of a field such as biotech will require a scientifically literate citizenry and a highly skilled scientific workforce. That is why the Amgen Foundation supports science education programs that provide pivotal, hands-on science experiences for students and meaningful professional development opportunities for teachers.

JEFFREY T. WALSH is Chief Operating Officer of Bluebird Bio, which is developing innovative gene therapies for severe genetic disorders. For more information, visit bluebirdbio.com.

1. The ever-evolving regulatory landscape and regulatory reform will continue to be key drivers for our industry. As regulatory authorities maintain their vigilance around effective and, most importantly, safe therapies, the pharma industry must continue to maintain patient safety as a No. 1 priority, but also to shift attention to diseases that today remain untreated or poorly treated. We must strive to innovate with transformative therapies that focus the attention back on delivering unparalleled efficacy to patient groups that need it most.
2. The increasing focus of big pharma and big biotech on rare disease indications and personalized medicine will continue to drive both biotech innovation and overall industry deal flow. Personalized medicine will come from genetic subsetting of larger diseases or single diseases that are naturally genetic in nature, such as severe monogenic diseases. Technologies, such as gene therapy, that can effectively address a specific cause of severe and rare genetic diseases and also offer the potential for a broad platform to attack many severe genetic diseases could prove to be the real value drivers.
3. We need to continue to re-establish and build pharma and biotech credibility over the next five years. As an industry, we've been challenged in this regard, and, in that process, we have forgotten about the true value and purpose of our industry, namely to have a profound ability to transform the lives of patients and to realign the price-to-value ratio. As an industry, we need to invest in the technologies, companies, and platforms that provide the breakthroughs to transform the lives of patients. Gene therapy is one of the promising technologies with the potential to drive innovation and opportunities to deliver great benefit.

> **"Trying to be all things to all people will be a recipe for extinction. The first business objective is to redefine the business model in light of relentless internal and external pressures."**
>
> **DAVE ORMESHER** / closerlook

tween people," she says. "From the very beginning, good partners demonstrate willingness to recognize and rely on others' strengths to solve challenges. An unwavering focus on the end goal of creating new and novel therapies for patients is essential to navigate through change and challenge."

For Lyn Baranowski, VP, business development, at Pearl Therapeutics, the most important factor to consider when considering potential partners is competency and experience in the field, which includes development and sales/marketing experience, knowledge of the key opinion leaders in the space, and familiarity with the FDA division responsible for regulatory approval.

Ken Kramer, Ph.D., senior VP and medical director, at Alpha & Omega Worldwide, part of The Core Nation, agrees that the major stakeholders at all stages of drug development should always be represented at the partnership table, including scientists, clinicians, marketers, payers, patients, and their advocates, to name a few.

"Each of these groups should have an active voice during drug development or companies risk miss serving the needs of one or more key audiences," he says. "We need to start thinking of these groups not as isolates but as a living ecosystem. An ecosystem flourishes because segments with different responsibilities work together toward a common good, while still enjoying some individual benefits. There is no shame in reaping the rewards of hard work as long as no single group profits at the expense of another. This is a lesson that needs

to be relearned, because a successful new drug benefits everyone."

Ms. Baranowski agrees that working collaboratively with all stakeholders is critical to future success, from the FDA, to all components of the healthcare delivery system, to patient groups.

"The needs and demands of each one of these constituents should be factored in at all stages of development," she says. "We have taken a thoughtful and careful approach, including communications with the FDA from the beginning, which has helped inform our development plans. Key opinion leaders in the respiratory field and in the inhaled drug delivery space have played integral roles in building our company over time. Their regular involvement allows us to capitalize on a broad base of expertise to refine our plans. Ultimately, we are all in this business to deliver promising drugs to patients and improve their health and lives, so working together with patient groups helps keep our plans aligned and focused to achieve success."

Creating a Culture of Innovation

In BBK Worldwide's 30 years, the company has found the following tenets have been especially powerful when it comes to creating a culture focused on innovation:

- Just because it's working doesn't mean it shouldn't be broken as a step toward making it work better.
- Seek out people who have grown up in the era of collaboration; these young professionals never had to mistake memorization for idea generation.
- Hire smart people who aren't afraid to actually apply the scientific method to the business aspects of drug discovery and development.
- Don't seek consensus; relentlessly pursue diversity of experience, perceptions, beliefs, and skills.
- Insist on time for conversations. Throw away the rules for a well-organized meeting and don't end the discussion until the group has identified at least two game-changing ideas.

Source: BBK Worldwide.
For more information, visit bbkworldwide.com.

Joan Bachenheimer, Co-Founding Principal, BBK Worldwide

Adjusting the Model

Mr. Ormesher says although it may be several years before we begin to see the new commercial landscape for the pharmaceutical industry take shape, change is inexorable.

"The simple commercial model of research-based small-molecule manufacturers selling to institutional buyers will experience its own Cambrian explosion into multiple business model species," he says. "This will require sober choices about target markets — how value is measured — and core competencies — how value is created. Trying to be all things to all people will be a recipe for extinction. The first business objective of life-science leadership will be to redefine the business model in light of the relentless internal and external pressures."

Ms. Buck Luce says the most important factors driving change in the life-sciences industry is the reality that the payer, provider, and life-sciences business models are all broken at a time when the changing demographics are making the current cost curve of healthcare beyond the future reach of government and family budgets.

"The hurdles are higher everywhere," she says. "The FDA keeps moving the goal posts; reimbursement is tougher. The healthcare industry has historically been centered around products and services not patient outcomes. As a result, business models and funding have been built around volume not value. Life-sciences companies now must adapt to an environment where success will be based not on what product is produced, but how well companies can demonstrate improvements in health outcomes."

In a world increasingly defined by resource constraints, an important objective will be to reduce the overall cost of maintaining a healthy public.

Mr. Ormesher says in the past, pharmaceutical products were largely defined by their ability to cure or manage a disease, and cost was a secondary concern. This is quickly evolving among payers, both private and public, to a measurement of value in terms of patient health benefit per unit cost.

"For the pharmaceutical brand, this perceived value will come in one of two flavors: either low cost or extraordinary benefit — pick one," he says.

Outcomes, Outcomes, Outcomes

Most experts agree that the future path to success is paved with research that demonstrates improved patient outcomes.

"Rapid experimentation is a key part of successfully adapting to the changing life-sciences ecosystem," Ms. Buck Luce says. "While there is no one-size-fits-all business model, we are seeing a significant increase in the number of companies experimenting with business models that utilize a holistic approach to improving patient outcomes, be they disease management, coordinated care, or expanded interventions across different stages of care.

"Adapting to an outcomes-focused environment will also require life-sciences companies to explore radical collaborations with the nontraditional players increasingly targeting healthcare, and to leverage the investments these players have already made in technology platforms and network," she continues. "Not invented here was once an admission of inadequacy in this industry. In Pharma 3.0, it will be a source of pride."

Harry Greenspun, M.D., senior advisor, health care transformation and technology, at the Deloitte Center for Health Solutions, believes it's not so much a 3.0 model but a "N.0" model and beyond as the concept constantly evolves.

"The activity and economic model in place for pharmaceutical companies today is not one that pays for outcomes," he says. "Healthcare is shifting toward delivering value through clinical integration and assuming financial risk. As ACOs and similar models proliferate, for the industry to do better, companies needs to understand how to engage with these organizations where outcomes are a major part of the proposition."

Dr. Greenspun adds that it will be key for companies to access objective, comprehensive, statistically significant real-world information in a way that allows them to generate the necessary insights to support these decisions.

"We live in a world where there can be upward of 15 drugs that are approved and marketed for a single condition," Dr. Kramer says. "This has created legitimate debate over which drugs should receive preferred payer

coverage. However, the available data may have difficulty supporting such important decisions. Registration trials for these drugs were designed for approval and not comparison, because a limited set of endpoints was used. Payers, needing to make decisions that involve thousands of lives and millions of dollars, are now asking for comparative data. They want to know which drug will give them the most bang for their buck. This need is in part being satisfied by the Institute of Medicine's Comparative Effectiveness initiative, but these are mostly retrospective analyses. Going forward, pharmaceutical companies will have to add outcomes endpoints to the usual cadre of efficacy, tolerability, and safety standards when designing clinical trials. This will likely add time and expense to medications development, but in a world of shrinking coverage, this becomes the new cost of entry."

Mr. Ormesher agrees that life-sciences companies need to learn how to become outcomes-based.

"As Ed Bennett recently remarked, the entire healthcare reform law can be boiled down to four words: 'no outcomes, no income,'" Mr. Ormesher says. "Outcomes are not the same as efficacy. Soon CMS will be paying providers based on outcomes, and physicians will insist that the pharmaceutical company is able to deliver measurable improvements. Whether pharmaceutical companies evolve from strictly delivering products to healthcare solutions or whether they learn how to partner with diagnostics, medical device, food, and exercise companies, marketers will need to learn some new moves."

Richard Gliklich, M.D., president and CEO of Outcome, says pharma will need to generate data that are timely (i.e, available at the time of a formulary or reimbursement determination), relevant (i.e., outcomes of relevance to the payers), and robust (since the payers already have data), the pharmaceutical company data need to be better to gain the attention of the payers.

"This means companies need to plan earlier for outcomes data collection, more sources of data that are generalizable to the payer's population, such as from observational studies and electronic data sources, and more clinically rich data that are a step above the claims data that the payers already have access to," he says. "If payers move toward more conditional reimbursement programs, then ongoing generations of data may become the standard for obtaining and maintaining formulary position."

Ms. Buck Luce has observed that across the globe, governments are responding to budgetary pressures by clamping down on drug prices and using outcomes-based criteria to decide where to cut.

"As a result, companies will need to find ways to harness the explosion of data now available to help drive real-world insights into the efficacy of their drugs," she says. "In addition, using new technologies to drive patient compliance will also be a vital catalyst for companies to achieve the type of differentiated outcomes demanded by payers."

In this "prove it or lose it" environment, Ms. Buck Luce says, pharmaceutical companies will need to take such steps as pharmacoeconomic analyses, comparative effectiveness research, and data mining using digital health records to demonstrate the superiority of their products.

"Companies may also need to take on more risk that a treatment may not work by agreeing to outcomes-based pricing approaches," she says. PV

WHITEPAPER

IDENTIFYING STRATEGIC PARTNERS FOR PRODUCT DEVELOPMENT

Dave Fishman, Snowfish LLC

bit.ly/Snowfish-papers

EXPERTS

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