In The BOARDROOM

From defining and redefining organizational business models for big pharma, biotech, and emerging pharma, to tactical decisions related to developing generic defense strategies, to improving communications and corporate reputation plans, to grappling with technology issues. Today's pharmaceutical leaders are relying on business-savvy solutions.

DR. DANIEL CARR
Javelin Pharmaceuticals

For small specialty pharma companies, the matrix organizational structure is one that allows them to respond quickly and adapt to the shifting demands placed upon them.

BUSINESS AND ORGANIZATIONAL MODELS

According to some industry analysts, the new pharma business model will focus on innovation, compliance initiatives, enterprisewide technology solutions, and customer-focused approaches, as companies move away from relying heavily on blockbuster products. Additionally, the increased pace of merger and acquisition (M&A) activity in 2005 has forced executives and business unit managers to grapple with the challenges of effectively managing organizational change.

GOLDSTONE. Recent years have marked the ascent of the brand — something that will continue apace as the industry recognizes the potential of brands, realizes their importance to the business, and understands the reality that their brands, both product and corporate, will have to work much harder and longer as companies face a future of less well-stocked pipelines. The question is: will the industry be looking at $500 million blockbusters or a proliferation of "nichebusters" in the not-too-distant future?

BRADY. The fast-changing compliance landscape of the pharmaceutical industry will continue to drive internal evaluation of, and new investment in, systems and processes that better track and control interactions with healthcare professionals. In addition to federal laws and industry guidelines, such as OIG and the PhRMA code, individual state legislatures are enacting laws that impact those same interactions. To operate in a fully compliant manner, companies need systemic methods to meet the requirements of a number of authorities. Pharmaceutical companies will need to establish information-exchange processes and systems that span all divisions of the organization. In addition, businesses with a culture of proactive compliance management will invest in infrastructures or processes that ensure activity limits with healthcare professionals do not exceed limits. This can be accomplished through superior, enterprisewide information collection that is both complete and timely enough to prevent noncompliance. In addition to a comprehensive information-management system, a second critical factor to proactively manage healthcare professional relationships is improving the timeliness of the data that are used to manage a compliance program. Timely data are important to ensure limits have not been exceeded. Systems and processes that reliably monitor and alert companies when a limit is approaching is key to preventing noncompliance. Data that can be received in real-time and integrated into an enterprisewide information system will ensure compliant healthcare professional interactions across the entire organization.

RIABOV. Leadership in any organization needs to set the tone/parameters for all members of the organization to follow, for example: mission, vision, and values. If these are not clearly defined, communicated, and believed throughout the organization, fiefdoms or silos will thrive. How can companies break down the silos? If everyone understands the big picture of why they are there, it will lead to a natural progression of cross-functional teams from different departments, resulting in cooperation and coordination, and making use of the skills in the organization to create a strong, high-performing team.

CARR. For small specialty pharmaceutical companies, the matrix organizational structure is one that allows them to respond quickly and adapt to the shifting demands placed upon them. Communications are essential to Javelin and other small-cap companies. We have to tell our current shareholders where we stand on executing on our developmental plan, explain our vision to prospective investors, and inform those in the medical and

TIM NOFFKE
IPM

Companies recognize that good project-management practices provide the foundation for effectively managing entire portfolios throughout product life cycles.

scientific communities of our useful new products.

MANGIAVAS. There's something missing in many, if not most, life-cycle management plans — the R&D factor. Most life-cycle plans are synonymous with building and leveraging brand equity from prelaunch, launch, peak, and planning for the inevitable patent expiry. The missing link is R&D. Early life-cycle planning is as much an R&D imperative as it is a marketing imperative. Why? Who understands a given molecule better than the scientists who helped develop it? Who understands the potential application for a mechanism of action beyond a single therapeutic application? What additional development can be done to look at additional therapeutic areas?

M&A ACTIVITY

The average budget for a pharmaceutical company's business development group — the function that strikes deals with other drug companies — is $9 million, according to a report from Cutting Edge Information.

Pharmaceutical and biotechnology companies rely on deals with each other to broaden product pipelines, raise cash, and build lucrative, strategic partnerships. To make the most of hefty investments — **budgets can climb past the $50 million mark** for teams at the largest firms — some companies field highly specialized business development departments to bring in the best deals.

THERE ARE USUALLY THREE COMPONENTS IN SPECIALIZED BUSINESS DEVELOPMENT STRUCTURES

THE FIRST GROUP includes individuals who search for and evaluate deal opportunities. They pass on high-potential projects to deal negotiators, who work out contract details with the nascent partners. Finally, in an ongoing relationship, alliance managers take over to shepherd the project toward its finish line.

THIS LAST GROUP — alliance management — is the most rare component among pharmaceutical deal makers. In Cutting Edge Information's study, **67% of companies that formally review more than 20 deals per year have an alliance-management group**. Among companies that review between five and 20 deals, only **29% have alliance management specialists**.

"Alliance management is the final piece of the business development structure," says Eric Bolesh, lead author of Cutting Edge Information's report. "Formal alliance management groups tend to appear in relatively sophisticated organizations, and they command critical budget dollars."

According to Mr. Bolesh, it is common for these larger companies to **annually allocate between $4 million and $6 million to alliance management**, and the study's **highest-spending firm** reported an alliance-management **budget of $25 million**.

Source: Cutting Edge Information, Research Triangle Park, N.C.
For more information, visit cuttingedgeinformation.com.

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JEFF BRADY
Advanced Health Media

The fast-changing compliance landscape of the pharmaceutical industry will continue to drive internal evaluation of, and new investment in, systems and processes that better track and control interactions with healthcare professionals.

We need to think just as much about "molecule optimization" as we do about "brand optimization" to cover all bases. With fewer brands in development at a single company, looking at further development of an existing brand could be key to long-term commercial success. This may include reformulations or entirely new indications.

NOFFKE. Companies recognize that good project-management practices provide the foundation for effectively managing entire portfolios throughout product life cycles. Patent life starts when the patent is issued, not when the product is launched, so improving upon the historic 10 years to 15 years spent in development will certainly yield longer patent protection. According to an independent multi-industry study of 200 projects at 90 companies, compared with industry averages, a marginal increase in project-management maturity resulted in: 35% to 50% faster time to market, 75% better schedule conformance, and 60% less cost variance. In addition, project management puts focus and organization around the pursuit of life-cycle strategies, such as new indications and combination therapies, which can be initiated and explored earlier in the product's life.

HULSE. Driven by the constant need to develop new products and the industry's inability to develop the products without the assistance of biotechnology companies, M&A activity will continue in 2006. As a result, companies will acquire other large companies to mask their inability to develop new products, and they will acquire biotechnology companies to access new products.

J. RHODES. The pace of M&A activities will continue to increase during 2006. Recent trends suggest that the need for companies to fill pipelines, as well as leverage emerging technologies, will continue. This will lead to additional mergers and partnering within sectors and across sectors. As internal candidates offer fewer options, one means to expand the opportunities will be to continue to collaborate or be acquired. In certain sectors, mergers will continue to leverage new technologies by bringing greater capital to bear. I think this will be most prevalent in biotechnology, diagnostics, and specialty pharmaceutical.

DEFENDING BRAND REVENUE: PHARMACEUTICAL LIFE-CYCLE MANAGEMENT PLANNING

A recent report from Cutting Edge Information finds that 43% of global life-cycle management teams begin LCM planning for a brand during Phase I development.

One interviewed executive claims the decisions made during this early planning period are equally important as those made during a drug's final year of market exclusivity.

Early-stage life-cycle management planning typically involves determining a compound's proclivity for multiple formulations, multiple indications, and whether it can react well in combination with other compounds. Some companies even develop a target product profile before even development of the chemical entity begins. All the preparation involved in life-cycle management pays off years down the road as patent expiration approaches.

"Companies that wait until late Phase II or Phase III to start LCM planning cheat themselves," says Elio Evangelista, senior analyst at Cutting Edge Information. "By having a plan of action in place earlier, the scramble as products approach patent expiry is not as chaotic."

Source: Cutting Edge Information, Research Triangle Park, N.C.
For more information, visit cuttingedgeinformation.com.

BIOTECHNOLOGY BUSINESS

The biotechnology sector is reaching a new level of maturity and growth. In 2004, biotech companies raised $16.9 billion in capital in the United States and $3.4 billion in Europe, surpassing 2003 totals. Additionally, the production capacity for biopharmaceutical manufacturing is expected to expand an average of 48% over the next five years for mammalian and microbial production systems. Furthermore, biotech hotbeds are emerging in the Asia-Pacific region, particularly Japan, India, and China, while Korea and Singapore are creating niches in areas such as stem-cell research and manufacturing.

ZISSON. On the public-market side, we

MAUREEN MANGIAVAS

Hal Lewis

We need to think just as much about 'molecule optimization' as we do about 'brand optimization' to cover all bases.

expect that already public companies should be able to raise significant amounts of money at a relatively low cost of capital. This will be especially true in the private investment in public equities (PIPE) segment for smaller companies if hedge funds continue to invest aggressively in these types of offerings. For private companies seeking to go public, given the aftermarket performance of IPOs over the last 24 months, and for all but the most exceptional stories, we don't see any reason why buyers will alter their recent pattern of demanding big discounts from the initial filing range, leaving companies with smaller and more dilutive deals. For private companies raising money, many healthcare venture funds are flush with money. We expect that rounds can be done, but the bias will be against earlier stage companies where it is difficult for venture investors to deploy large amounts of capital quickly.

ROTHMAN. As biotech matures, certain approaches will be validated while others will fail. I expect that technologies that extend the dimensions of successful approaches will be well-received, while technologies that are currently little-known or unheard of will emerge and need to prove themselves. Similarly, business models that can prove themselves will succeed, while those built upon research paradigms that don't translate into sound business models won't.

HULSE. I expect the funding climate to continue to improve into 2006. The biggest challenge will be the continuing difficulty of obtaining adequate research coverage and investment banking support for many of the very large number of public biotechnology companies. Currently, tool companies and platform technology companies are continuing to lose favor in contrast to product companies. The need in big pharma for new products allows the product companies to focus on dis-

BIG PHARMA BUSINESS MODELS ARE EVOLVING

According to Wood Mackenzie's latest Horizons report, "It Ain't Your Parents' Pharma Industry Anymore," the future of new big pharma business models will be focused on innovation and customer-focused approaches, as they move away from relying heavily on blockbuster products.

Blockbusters can be the key to a company sustaining competitive advantage for a while; but without a diversified portfolio to protect itself, the company could find itself in financial difficulty when patents expire. Also, the number of blockbusters and the percentage blockbusters contribute to sales have decreased since the rapid growth of blockbusters in the industry in the late 1990s. Wood Mackenzie has identified three distinct business models the pharmaceutical industry may pursue in response to this decline of sales from blockbuster drugs:

1. A focus on key specialty audiences in marketing
2. A limited number of therapy areas in R&D
3. A much more customer-centric selling model

"For the past 20 years, the leading pharmaceutical companies have all looked very similar," says Dr. Keith Redpath, head life-sciences research for Wood Mackenzie. "They all had in-house R&D across many therapeutic areas, were vertically integrated, and their growth was driven by the blockbuster model — with one product accounting often for 30% or more of their sales. Now, these evolving models mean drug companies are beginning to look different."

Sales of pharmaceuticals are forecast to continue to grow, but sales from blockbusters are forecast to flatten over the next five years.

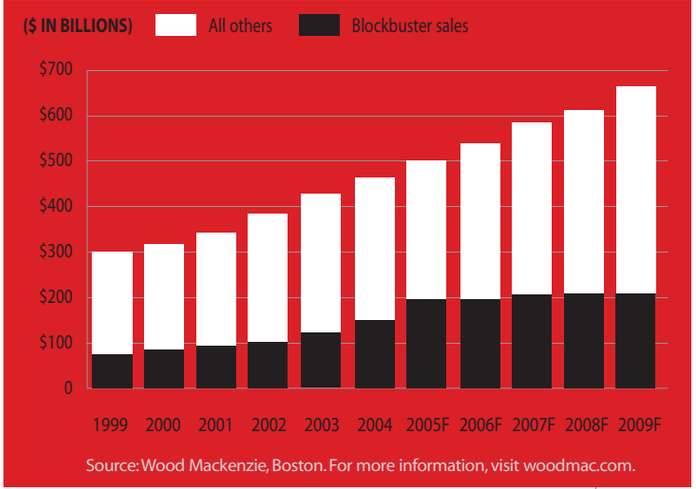
So does this mean the days of blockbusters are numbered?

"Maybe; maybe not," says James Featherstone, global head of consulting. "Blockbusters can be the key to a company sustaining competitive advantage for a while, but without a diversified portfolio to protect itself from patent expires, the company could find itself on the block for acquisition by larger and stronger players."

Innovation clearly holds the key. More than ever the industry needs to focus on science-driven strategies, targeted at fundamental product differentiation focused on the unmet medical needs of global markets.

Source: Wood Mackenzie, Boston.
For more information, visit woodmacresearch.com.

PHARMACEUTICAL SALES



Source: Wood Mackenzie, Boston. For more information, visit woodmac.com.

covery and preclinical development and strike early partnering deals. As a result, the fully integrated model is less appealing for biotechnology companies. A factor at this point is that acquisition plays a much greater role as a liquidity event than in past years.

SCOTT. Our Biotech Top 10 list includes both industry pioneers and emerging companies that are far from household names. These companies have been identified as key stocks based on their product pipelines, clinical successes, and the market potential for their lead drugs or candidates. The list is very interesting in its diversity. The companies we have selected as 'the most likely to succeed' run the gamut from Genentech and Amgen — solid, integrated companies with blockbuster drugs, strong earnings growth, and extensive pipelines — to StemCells and Geron — highly speculative, momentum plays full of promise but as yet unproven.

FREIMAN. I foresee 2006 to be a difficult year for sensible fund raising on the part of smaller biotech companies. Much of this will be influenced by the external environment that I believe will be quite bearish. There are, of course, a band of hearty investors in healthcare who are in it for the long haul. Even they, however, are not employing all their funds and have become much more selective in their investments. The major challenges for smaller and emerging companies will remain cash. If a company is not sitting with two years of cash, life is not going to be easy. The public-equity markets have not been kind to small companies attempting to go public. My company attempts to strike strategic investments, which are both nondilutive and at the same time collaborative. A second and constant challenge for small firms is to stay focused. It amazes me to see how many small firms are so easily diverted into side streets with their technologies.

GESSLER. In 1999 and 2000 funding was not an issue; rather, there was a volume of funding available ranging from private-equi-

MANAGING M&A HONEYMOON BLUES

The increased pace of merger and acquisition (M&A) activity in 2005 is again forcing executives and business unit managers to grapple with the challenges of effectively managing organizational change.

According to Best Practices, proven planning and management tactics are the key to merging different companies into a single, profitable entity.

Best-in-class organizations develop comprehensive integration models that map integration processes across the full organization. Advanced organizational design models are very effective at creating a high-level overview for executives while still delivering change management tools and programs to managers on the ground.

Leading companies recognize that retaining key leadership personnel from all organizations involved in the M&A is highly correlated to the timeframe and the perceived success of the integration process.

If post M&A rationalization action is required, best-in-class organizations downsize expeditiously and in parallel revise incentive and reward programs to motivate existing employees.

According to Best Practices, M&A teams can successfully manage a large-scale merger in just 3 to 6 months. Many handle less complicated mergers and acquisitions in as little as 1 to 3 months.

Analysis reveals how successful M&A teams communicate the value of their work to the companies they serve.

AMONG THE TOP TECHNIQUES

1. M&A teams use customized presentations to the management team.
2. They track and share success stories.
3. They provide ROI statements analyzing the benefits of their work.

FROM THE MANAGEMENT PERSPECTIVE AT MANY OF THE COMPANIES, SERVICE VALUE FOR AN INTEGRATION TEAM IS ASSESSED BASED ON THE FOLLOWING MEASURES

1. Speed of services completed against forecasted timelines
2. Cost savings
3. Discounted cash flow
4. ROI
5. Total cost

Best Practices underscores the importance of having a highly linked process chain: from pre-deal business development and integration planning to culture and personnel integration, customer relationship management, and technology and systems integration.

FOLLOWING FINDINGS EMERGED FROM ITS RESEARCH

▶ **BUSINESS DEVELOPMENT.** One company leverages knowledge from previous experiences and smoothes the road to success through the development and use of a cost template. This document can provide a loose checklist of activities and guarantee the financial resources for activities frequently overlooked in the planning, such as the funds required for relocation, paying the lease, or buying new, compatible office equipment.

▶ **INTEGRATION PLANNING.** The faster integration activities are finished, the more likely it is that the new company will prosper internally and externally. To this end, another benchmarked company employs a timetable that ensures completion of all primary tasks in three months after final negotiations.

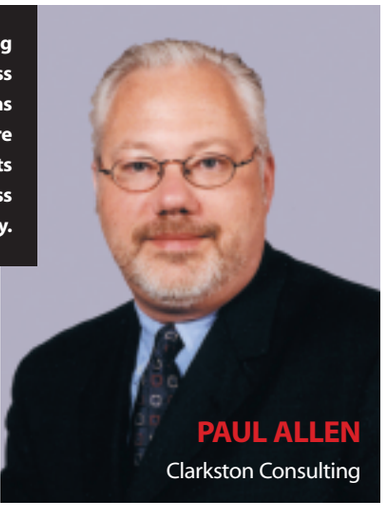
▶ **CULTURE AND PERSONNEL MANAGEMENT.** To help employees cope with stress, one top company uses an employee-assistance program. The human resources department highlights the signs of stress to managers. The managers can then direct stressed employees toward the program, or the employees can enroll of their own volition.

Source: Best Practices LLC, Chapel Hill, N.C.
For more information, visit best-in-class.com.

ERIC LANGER
BioPlan Associates Inc.

A major factor impacting production capacity expansion over the next five years will be the lack of trained and experienced production staff.

With biotech's market capitalization reaching $400 billion, the magnitude of business initiatives for emerging biotechnology firms can be overwhelming. Most are interdependent upon each other and projects expected to have high impact on business growth are given highest priority.



PAUL ALLEN
Clarkston Consulting

For the next few years, we should expect continued growth for the biotech industry, fueled in part by an increasing number of global alliances and partnerships, with the U.S. continuing to lead the industry.

ELLEN MILLER
Biosector 2

ty to debt financing. Ultimately, the public market — the IPO — was the exit for investors at the end of the investment tunnel. Clear avenues for liquidity helped fuel the staggering pace of innovation occurring in and around that time period. The pop of the tech bubble has significantly reduced biomedical investment possibilities, and they have yet to regain those 2000 levels. Recently, the funding markets have tightened and become far more demanding in terms of initial hurdle rates — the due diligence cost of entry. This means prospect enterprises must demonstrate — in greater detail than ever before — a viable business model, scientific, and clinical rationale; pathway to profitability; and, ultimately, an exit strategy. Despite these realities, 2006 may prove to be a turning point for investment seekers, and should be a better year for funding, irrespective of the size or maturity of a company. If capital is directed to enterprises with solid management teams, a proven track record, solid operating strategy, strong financial metrics, and clear approach-to-market, then not only are existing funding sources rewarded, but new funding sources come in looking to participate in this success. Then, with readily available liquidity, the entire industry moves forward. One of the current environment's big challenges is that most investors are only interested in companies with drugs in the clinic, typically in Phase II. This is likely to reduce truly innovative research and reward only incremental improvements to healthcare. It provides less incentive for companies to take risks. While investor sentiments do change over time, my anticipation is that this focus on companies with advanced clinical candidates is likely to persist.

TOP PHARMACEUTICAL COMPANIES FAILING TO DELIVER MAJOR NEW PRODUCTS

Despite significant investment in research and development, many leading pharmaceutical companies will fail to develop and market products with significant levels of revenue contribution, according to Wood Mackenzie.

Calculating the proportion of the company's forecast sales in 2009, which is derived from products launched in the previous five years, Wood Mackenzie has generated a Freshness Index for the top pharmaceutical companies in the world. A low Freshness Index occurs when the company is either launching no new products, or the revenue from new products are forecast to be low.

According to Wood Mackenzie, the poor revenue growth forecasts and low Freshness Indices for companies such as GlaxoSmithKline and Merck, which are focused on primary-care markets with large populations such as depression, gastric ulceration, blood pressure, and high cholesterol, suggests that these markets are currently very well served with safe and effective medicines.

Source: Wood Mackenzie, Boston.
For more information, visit woodmacresearch.com.

SALES FORECASTS, SALES GROWTH, AND FRESHNESS INDICES FOR THE TOP 10 PHARMACEUTICAL COMPANIES

2004 Rank	Company	Forecast 2009 Sales ($ in millions)	Sales Growth CAGR 2004-2007F (%)	2009 5-Year Freshness Index (%)
1	Pfizer	$41,950	-1.9%	10.1%
2	sanofi-aventis	$37,075	2.8%	10.2%
3	GlaxoSmithKline	$32,914	0.9%	6.5%
4	Hoffmann-La Roche	$29,705	11.2%	9.8%
5	Novartis	$28,486	6.0%	5.3%
6	AstraZeneca	$24,668	3.4%	0.6%
7	Johnson & Johnson	$23,914	1.6%	3.4%
8	Bristol-Myers Squibb	$21,974	7.3%	11.3%
9	Amgen	$21,857	17.0%	5.0%
10	Merck & Co.	$20,644	-2.1%	7.1%
	TOTAL	$669,945		

Source: Wood Mackenzie's Productview, April 2005.
For more information, visit woodmacresearch.com.

ALLEN. Biotech companies need to convert innovative science into sound business goals and create a successful transformation that bridges the gap between projects and go-to-market strategies. Goldman Sachs estimates that 35 new products with sales of at least $150 billion will reach the market, out of which 20 will be from biotechnology. Implementing an effective program management office (PMO) can alleviate risk and create the competitive advantages needed in the global marketplace. A formal PMO is an essential strategy designed to support the collaborative vision, prioritization, communication, and execution of projects. Most importantly, it will propel a company's executive alignment to achieve commercial success. With biotech's market capitalization reaching $400 billion, the magnitude of business initiatives for emerging biotechnology firms can be overwhelming. Most are interdependent upon each other, and projects expected to have high impact on business growth are given highest priority. Failure to meet deadlines for critical path initiatives can result in missed product launches, stockholder dissatisfaction, FDA challenges, and financial strains. By developing a PMO-oversight organization, a company assigns the management of complicated projects that integrate people, processes, and technologies thus enabling the development group to stay focused on science and innovation. The PMO does not replace the need for executive decision-making. In fact, executive

THE EMERGING GLOBAL LABOR MARKET: DEMAND FOR OFFSHORE TALENT IN PHARMACEUTICAL SERVICES

Global resourcing in the services portion of the pharmaceuticals sector has been done for decades as companies captured the benefits of centralizing their research in industry hot spots to leverage top scientific talent.

As the pharma industry has begun to experience pricing pressure and reduced profits, offshoring has become an increasingly important lever for companies to reduce cost and enhance revenue. While many of the leading players have set up pilot offshoring programs (either captive or through vendors), no pharma company is near reaching the theoretical maximum potential. The degree of adoption among high-wage countries is currently at 0.7% of employment but is projected to double in five years. But as this pressure continues pharma companies will likely overcome the barriers to global resourcing to realize the potential benefits.

Pharma employed in 2003 about 1.7 million people worldwide. In 2008, this number is projected to be about 2.0 million, a 2.8% annual increase driven by growth in pharmaceutical sales in both developed and developing nations and reduced by increasing productivity.

The theoretical maximum for globally resourced labor in pharma is 13% of all positions in the industry, or 19% of service (non-manufacturing) positions. The highest potential for global resourcing lies in IT services, research and development (R&D), commercial analytics, and general and administrative (G&A) back-office functions. In contrast, positions that need to remain local are those that interact with regulators. The global resourcing of manufacturing is not evaluated in the study as it is not a service function and thus out of scope. The occupations associated with functions that are more amenable to global resourcing include generalists, life-science researchers, IT engineers, and support staff.

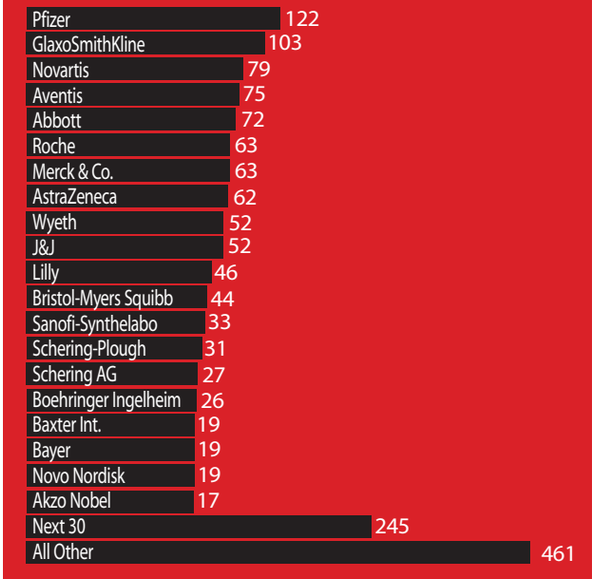
In response to declining profit margins and rising cost pressure, companies are now experimenting with or considering global resourcing. Global resourcing in pharma is only occurring in pilot programs led by large U.S. and Western European companies. In contrast to a maximum potential of 238,000 FTEs, an estimated 10,000 FTEs are globally resourced from low-wage locations, equal to 1.1% of service employment in developed countries.

Adoption of global resourcing in the pharma industry is driven by the cost differential between high-wage and low-wage countries, time to market, and increasing cost pressure. Conversely, product regulation in home countries, attractiveness of alternative profit-maximizing strategies, and the suitability of processes to support global resourcing are the primary barriers limiting the growth of adoption. Global resourcing will become an increasingly important source of value for the industry. Offshoring is expected to increase 16% annually, amounting to 21,000 employees in 2008.

GLOBAL RESOURCING POTENTIAL

Of the expected 2 million jobs in the pharma sector in 2008, 13% could be globally resourced, representing 254,000 employees. This translates to 19% of service employment (i.e., excluding employment dedicated to manufacturing).

59% OF EMPLOYMENT IS CONCENTRATED IN THE TOP 20 COMPANIES



Notes: Numbers are in thousands. In 2003, worldwide employment was about 1.7 million.
Sources: Compustat, Hoovers.com, Company Websites, IMS 2003 World Report, and McKinsey Global Institute analysis

sponsorship is critical to the success of a PMO organization. It is an advisory role established to execute the go-to-market strategy of a biotechnology company that must include a team of highly skilled project managers to lead programs that meet and exceed the goals set forth by the company.

ADITYA. Once biopharmaceutical developers thresh out a solution for meeting stringent regulatory requirements by hiring expert personnel and installing sophisticated facilities, the biological manufacturing processes — especially for monoclonal antibodies — are expected to become a lot simpler. This will encourage the development of several new biopharmaceuticals. While new technologies for identification of novel biopharmaceuticals will continue to emerge, a variety of supportive production technologies enable a growing pipeline of novel therapeutics. Developments in bioprocess technology have resulted in high outputs, thereby minimizing cost and time.

HULSE. Since the largest share of new biopharmaceutical products are coming out of biotechnology companies rather than big pharma, I would expect greater use of contract manufacturers. For biotechnology companies, the major challenge is to identify competent contract manufacturers.

ROTHMAN. I expect contract manufacturing to increase as small companies with good ideas develop their technologies for the market — especially as long as biotech continues in its role of off-balance sheet R&D for big pharma — since biotech cannot typically afford the investment in production capabilities. Cutting-edge

IN FTE TERMS, R&D IS THE FUNCTION WITH THE HIGHEST GLOBAL RESOURCING POTENTIAL

Share of employment %	Commercial (40%)	Manufacturing (31%)	Research & development (15%)	G&A (6%)	IT services (3%)	Procurement (3%)	Supply-chain management (2%)
Typical offshoring activities	Marketing/ customer analytics Salesforce support	N/A*	Data management & analysis Clinical trials Payroll	Accounting General support	Application development & maintenance	Transactional ordering Global contract negotiation	Forecasting Global logistic planning
Share of function that can be globally resourced	5.3%	N/A*	39.7%	30.0%	61.0%	29.0%	12.4%
Impact on global employee demand	2.1%	N/A*	5.9%	1.8%	1.8%	0.9%	0.2%
Employees who could be globally resourced in 2008 (in thousands)	42	N/A*	118	33	36	17	5

Notes: Of the total expected demand of 2.0 million employees in 2008, 254,000 could be resourced globally (12.8% of industry employment, 18.5% of non-manufacturing employment). This represents the theoretical maximum not considering any supply constraints, This does not consider manufacturing positions. * Global resourcing potential not evaluated as this is not service employment and is therefore out of scope.

Source: McKinsey Global Institute Analysis, Boston. For more information, visit mckinsey.com.

FAST FACTS

- Pharma employed about **1.7 million** people worldwide in 2003. In 2008, this number is projected to be about **2.0 million**, a 2.8% annual increase.
- The top 20 pharma companies represented **59%** of global employment in 2003. In addition to the majority of sector labor located in relatively few large players, **79%** of employment is concentrated in developed nations.
- Only **21%** of industry employment is outside Europe, the United States, and Japan, reflecting **0.03%** of nonagricultural employment. The United States, in contrast, holds **41%** of industry employment, reflecting **0.5%** of nonagricultural employment.
- Pharma sales per capita in the United States were **70 times** that of India and **13 times** that of China in 2003. Germany was more in line with the United States, with sales per capita at **81%** of U.S. levels. This concentrated employment is in part a consequence of the agglomeration of players around innovation centers.
- Employment in the pharma sector is concentrated in three core functions: commercial (**40%**), manufacturing (**31%**), and research and development (**15%**). Sales agents represent the largest subfunctional group, reflecting **88%** of commercial function, or **35%** of total industry employment. The remaining **14%** of employment is engaged in backoffice functions such as G&A (**6%**), IT (**3%**), procurement (**3%**), and supply-chain management (**2%**).

Source: McKinsey & Co., Boston.
For more information, visit mckinsey.com.

The largest potential for global resourcing lies in IT, R&D, and commercial analytics. Despite the low global resourcing potential in the commercial function (5%), the large amount of employment allows for a significant number of employees in this function to operate remotely. Functions that have no potential to be relocated are limited to the portion of the commercial function concerned with regulatory issues and distribution center operations.

CURRENT DEGREE OF GLOBAL RESOURCING

A significant movement toward global resourcing has already occurred. Most of the top, global pharma companies either have pilot programs in place or have begun to offshore portions of amenable functions. As put by one interviewee, "The question is not anymore whether pharma companies should offshore or not. The questions are what, when, and where to." In 2003, an estimated 10,000 FTEs were offshored, representing 0.7% of employment in developed countries (1.1% of service employment in developed countries).

Source: McKinsey & Co., Boston.
For more information, visit mckinsey.com.

A.N. ADITYA
Frost & Sullivan

Emerging stem-cell research has led to development of novel biodrugs. Applications include gene therapy, tissue engineering, neurological therapies, bone and cartilage repair, cancer, cardiovascular disease, diabetes and other autoimmune disorders, wound healing, and cell replacement for failing organs.

R. DOUGLAS HULSE
Hemispherx

Since the largest share of new biopharmaceutical products are coming out of biotechnology companies rather than big pharma, I would expect greater use of contract manufacturers. For biotechnology companies, the major challenge is to identify competent contract manufacturers.

technologies that may sound like science fiction to the layman will likely be accepted if their results are good and costs affordable. But be prepared for a backlash in the event of untoward events. A potentially life-saving technology that is shown to improve survival and/or the quality of life in hundreds or thousands of patients may be overwhelmed by a single adverse event that can frighten people, especially in the manner in which media events are presented.

LANGER. A major factor impacting production capacity expansion over the next five years will be the lack of trained and experienced production staff. In fact, almost 40% of the respondents to a recent survey indicated this would be a critical issue. In addition to industry expansion, a significant factor reducing the demand on capacity is that biopharmaceutical developers are experiencing results from efficiency-based R&D aimed at producing greater yields.

E. MILLER. While the United States has been the clear leader in the biotech arena for more than two decades, biotech has been burgeoning in the Pacific Rim for the past few years for many reasons. The region has the institutions and the scientists, many of whom have trained in the United States, to support this cutting-edge research. In recent years, the Pacific Rim has been discovered by hedge funds, venture capitalists, and other investors as potentially prosperous, untilled soil. The influx of financial capital has enabled these institutions and scientists to expand their programs and advance their research exponentially. In addition, these countries have the advantage of operating in a less restrictive regulatory environment than in the United States and in Europe — from the scrutiny of clinical trials, to the process to review and approve new drugs, as well as their unrestricted research frontier that enables concentration on two hot areas in biotech, stem-cell research and cloning. Finally, there is a significant financial advantage in Pacific Rim countries, where the cost to conduct research is substantially less than in the United States and Europe. The increase of global competition in the biotech field is not only healthy, but necessary to push the agenda of discovering newer therapies that address unmet medical needs, are safer and better tolerated, and ultimately, are more affordable. For the next few years, we should expect continued growth for the biotech industry, fueled in part by an increasing number of global alliances and partnerships, with the United States continuing to lead the industry.

ROTHMAN. Innovation will increase and cost will decrease. U.S. firms will find that they are in increasing competition in the arena of ideas, and challenged to compete economically.

HULSE. In all of the areas indicated in the Asia-Pacific region and a few in Europe, such as Ireland, there is significant public funding to sup-

THE CENTIENT BIOTECH TOP 10

The Centient Biotech Investor released its Top 10 Biotech list, identifying the 10 companies it believes will outperform the biotechnology sector as a whole over the next 12 months.

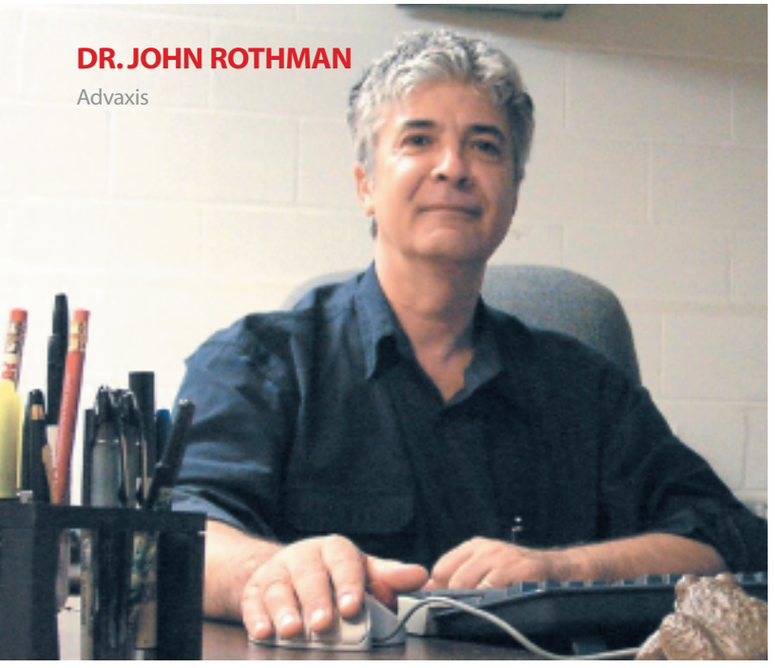
The Centient Biotech Investor has been publishing investment analysis and advice for nearly two years and registering a high percentage of accurate calls, but this is the first time the newsletter has gone on record with a specific list of recommended companies.

"The one thing all of our Top 10 biotechs have in common is that we expect each of them to do well over the next 12 months," says Frank Eeckman, M.D., Ph.D., editor of The Centient Biotech Investor. "But biotech is a volatile industry, and a single disappointing clinical trial or major adverse event can quickly turn a winner into a loser. So only time will tell."

▶ **AMGEN.** The No. 1 or No. 2 biotech company, depending on who's counting. Very strong earnings from its epo franchise, plus the epo drugs are winning expanded indications. Profit margins of more than 30% yield billion-dollar profits each quarter, and the company forecasts growth in revenue/earnings at a high-teens rate.

▶ **AMYLIN.** Received FDA approval for two diabetes drugs so far this year: Byetta for type 2 diabetes before patients begin taking insulin, and Symlin, used as a mealtime adjunct to regular insulin. Recent positive Phase II trial of a once-weekly form of Byetta gives hope that the drug will win wider adoption.

▶ **CELGENE.** Thalidomid drives Celgene's current revenue growth. It's used for leprosy and off label for multiple myeloma, a disease with no alternative treatment. Trials for Revlimid, a new analog of Thalidomid with fewer side effects, were recently halted, but this should be a temporary setback. Thalido-



DR. JOHN ROTHMAN
Advaxis

Innovation will increase and cost will decrease. U.S. firms will find that they are in increasing competition in the arena of ideas and challenged to compete economically.

ALEX ZISSON
Thomas, McNerney & Partners

For private companies raising money, many healthcare venture funds are flush with money. We expect that rounds can be done, but the bias will be against earlier-stage companies where it is difficult for venture investors to deploy quickly large amounts of capital.

The companies we have selected as the most likely to succeed run the gamut from Genentech and Amgen — solid, integrated companies with blockbuster drugs, strong earnings growth, and extensive pipelines — to StemCells and Geron — highly speculative, momentum plays full of promise but as yet unproven.

GREG SCOTT
Centient Consulting

mid and Revlimid are also potent antiangiogenesis drugs with promise for other uses.

▶ **ENCYSIVE.** Company awaits FDA approval of its lead product, Thelin, a novel molecule that produced positive results in its pulmonary arterial hypertension (PAH) trial, with a PDUFA date of March 24, 2006. Europe has also accepted its application. With the recent drop, this may be a buying opportunity.

▶ **IMCLONE.** Already profitable with Erbitux, a treatment for colorectal cancer, the company is seeking expanded indications for the drug and recently announced a partnership with UCB to develop a novel anti-angiogenesis cancer drug, a compound similar to Erbitux. The company may be undervalued because of the Martha Stewart debacle.

▶ **GENENTECH.** The other major biotech after Amgen. Reporting blowout numbers again for Q3 05, its cancer drugs go from strength to strength. Avastin is leading revenue growth, and it, Herceptin, Rituxan, and Tarceva are all being tested for new indications. And Lucentis looks like best-in-class for age-related macular degeneration. With all this going for it, Genentech is likely to be a strong near-term and long-term performer.

▶ **GERON.** Originally a gerontology company focused on telomerase, Geron is now riding the stem-cell wave, having acquired groundbreaking IP from the U. of Wisconsin. The company also owns three major types of human neural cells from embryonic stem cells. Drugs are in early-stage development, which makes it a higher risk.

▶ **GILEAD SCIENCES.** Gilead is steadily profitable with its HIV drugs. The company makes regimens easier to follow, combining compounds into a single tablet, while it develops more effective compounds. Its lineup includes Viread and Emtriva for HIV, Hepsera for Hepatitis B, AmBisome for fungal infections, Vistide for CMV retinitis, plus Tamiflu for influenza, which is gaining world-wide attention with the rising avian flu concerns.

▶ **JOHNSON & JOHNSON.** The pharmaceutical equivalent of a 4-wheel drive SUV – big, with something going on at each corner. Its diversified model includes biotech, pharma, over-the-counter, and medical devices — all growing steadily. The $25 billion Guidant has slowed the stock rise, but its stents are potential industry beaters. J&J is a long-term growth company without the major drama of pure-play biotechs.

▶ **STEMCELLS.** StemCells aims to be first in the clinic with a stem-cell treatment, proposing to inject purified human neural stem cells into children suffering from Batten's disease, a fatal deficiency of lysosomal enzymes in the brain. Recently the company signed a cross-licensing pact with British-based ReNeuron to exchange technologies. The company has IP in the form of stem-cell lines that could generate near-term revenue.

Source: Centient Consulting Inc., San Diego.
For more information, visit biotechinvestor.com.

port biotech. In the near term, this will provide an opportunity for U.S. and European companies to sell or partner new technologies for which they cannot find local funding.

▶ EMERGING COMPANY STRATEGIES

The funding/financing environment for smaller and emerging companies in 2006 is expected to remain relatively the same, even as these companies face the same challenges as their larger peers.

MIDWEST WILL BE NEXT BIOTECH HOTBED

The Midwest's biotechnology parts are greater than its whole right now, says G. Steven Burrill, CEO of Burrill & Company.

The Midwest is not the first place people think of when considering centers of biotechnology excellence. Most of the biotech activity is concentrated on the East and West coasts, but it's really more of an awareness issue than it is a fact issue.

"The Midwest is broadly very involved in the life-sciences industry — medical devices, diagnostics, biopharmaceuticals, agricultural technology, and industrial biotechnology all thrive," Mr. Burrill continues. "The region is home to literally hundreds of life-sciences companies, and medical devices in particular is one of its fastest growing sectors."

According to Mr. Burrill, growing a regional center of excellence in biotechnology that will be internationally competitive requires commitment; collaboration of research institutions, venture capitalists, and the financial community; big pharma, diagnostic, device, and healthcare focused companies, politicians who provide a stable and supportive tax, financial, and regulatory environment; and a long-term perspective.

"The Midwest is well-positioned in all these areas, with its large, world-class companies in both medicine and agriculture, top-tier research institutions generating a steady stream of innovation, and a culture that's beginning to encourage development of exciting new biotechnology companies," Mr. Burrill says.

WHILE IT IS DIFFICULT TO GET AN ACCURATE PICTURE OF THE TRUE BIOTECHNOLOGY INDUSTRY IN THE MIDWEST BECAUSE EVERY STATE CLASSIFIES LIFE-SCIENCE COMPANIES IN DIFFERENT WAYS, THERE IS PLENTY OF ONGOING ACTIVITY:

▶ **ECONOMIC AND POLITICAL LEADERS** in the Midwest have targeted the life sciences as an engine of growth, and several Midwestern states have established specific funds to invest in the life sciences.

▶ **THE MIDWEST IS HOME TO LIFE-SCIENCES INDUSTRY LEADERS** such as Abbott Laboratories, Archer Daniels Midland, Baxter, Cargill, Dow AgroSciences, Lilly, 3M, Guidant, Medtronic, GE Medical, Monsanto, and Procter & Gamble.

▶ **A GROUP OF WORLD-CLASS ACADEMIC RESEARCH INSTITUTIONS** is helping to fuel innovation; the Big 10 universities all enjoy nationally recognized research programs.

▶ **MORE THAN 300 DEDICATED BIOTECHNOLOGY COMPANIES ALREADY EXIST** in the Midwest, representing 21% of total U.S. biotech companies, about 1,400. There are 12 public biotech companies, about 3% of the U.S. total.

▶ **LEADING MIDWEST BIOTECH PLAYERS (PUBLIC OR PRIVATE) INCLUDE**: Aastrom Biosciences, Advanced Life Sciences, BioSante Pharmaceuticals, Genomic Solutions, IDEXX Corp., MGI Pharma, Neopharm, Northfield Labs, and Third Wave Technologies.

▶ **THE $1 BILLION MICHIGAN LIFE-SCIENCES CORRIDOR (MLSC)** has become a catalyst for the industry, producing collaborations between academic and commercial sectors.

▶ **MEDICAL ALLEY IS A 350-MILE-LONG CORRIDOR** in Minnesota that is the location of thousands of companies and institutions in the medical field. The medical-device industry is one of the Midwest's unique strengths and a field that is quickly attracting capital investments from some of the nation's leading VC firms.

▶ **THE UNIVERSITY OF WISCONSIN AND THE UNIVERSITY OF ILLINOIS URBANA-CHAMPAIGN** are extremely strong in agricultural biotechnology. They support research in both plant and animal applications that are dedicated to improving yield and quality of products, and they house a number of germ plasm collections.

▶ **THE UNIVERSITY OF MINNESOTA,** the Mayo Clinic, and the State of Minnesota have created the Minnesota Partnership for Biotechnology and Medical Genomics.

▶ **WISCONSIN IS INVESTING UP TO $750 MILLION**, including more than $500 million in new facilities and direct research support for scientists at UW-Madison, especially in stem cells. James Thomson and his collaborators, the University of Wisconsin - Madison has been a leader in this exciting area.

▶ **CHICAGO BOASTS SOME OF THE LEADING RESEARCH AND MEDICAL INSTITUTIONS** in the United States: the University of Chicago, and Northwestern University, Argonne National Laboratory, University of Illinois-Chicago, Loyola Medical School, Finch University- Chicago Medical School, and the Fermi National Accelerator Lab (operating the world's highest energy particle accelerator). Argonne operates the $20 billion advanced photon source, a key tool for protein and proteomics research.

Source: Burrill & Company, San Francisco.
For more information, visit burrillandco.com.
Editor's Note: More than 25,000 registrants are expected to attend BIO 2006 in Chicago in April 2006.
PharmaVOICE is exhibiting at this prestigious conference and looks forward to seeing you there.

GESSLER. Small organizations face many of the same development and regulatory challenges as big pharmaceutical companies. Both want to develop better, safer drugs more quickly and at reduced cost. Development is going to continue to be expensive and time-consuming, and regulatory hurdles will always be there. The differences lie in the effect of development and regulatory hurdles on the limited resources of small companies. One failed drug is a negative outcome for any company, but while that event may cause a big pharmaceutical company's stock to go down, it can easily sink a small biotechnology company. One thing is true for both the large and the small organizations: they can't do everything well in-house. To decrease the time and costs of drug development, big pharma and biotech companies need to find talent and technology outside their walls. Ultimately, development and regulatory hurdles combined with limited resources create the mandate for new ideas and solutions. We help drug developers — large and small — overcome those development and regulatory hurdles. We have been, and will continue to be, an important catalyst for creating change in the industry.

MAJOR PHARMA INVESTS IN BIOTECH

▶ WYETH OPENS WORLD'S LARGEST INTEGRATED BIOTECH PRODUCTION FACILITY

In September, Wyeth formally opened its Grange Castle biotech production facility in South County Dublin, Ireland. **The new 1.2-million-square-foot campus** is one of the largest integrated biotech manufacturing facilities in the world and is expected to produce some of the company's most innovative products.

"The work performed in this facility will lead the way to better and more innovative healthcare through the application of biotechnology developed right here, in Ireland," says Bernard Poussot, president of Wyeth Pharmaceuticals. "We expect to continue to invest in this new state-of-the-art facility and to make Grange Castle one of our key biotech development, production, and distribution efforts in the coming years, complementing our U.S. presence in Andover, Mass."

Through sustained investment over the last decade, Wyeth has become one of the largest global biotech companies in the world and the fastest-growing pharmaceutical company in Europe. The company has emphasized a sustainable new paradigm, which combines the biotech culture with the resources and global reach of a large pharmaceutical company — a model for success in a challenging and changing industry. Biotech drugs are a rapidly growing segment of Wyeth's more than $17.4 billion business and include such innovative products as Enbrel (etanercept), ReFacto Antihemophilic Factor (Recombinant), BeneFix Coagulation Factor IX (Recombinant), and Prevenar 7-valent pneumococcal vaccine for children.

Wyeth invested almost $2 billion in the Grange Castle facility, where site development work began in October 2002. The campus at Grange Castle, which employs more than 1,000 people, comprises three separate facilities — a drug-development unit, a drug substance site, and a drug product facility. These facilities will go into production on a phased basis over the next four years. With the addition of Grange Castle to Wyeth's existing manufacturing sites in Ireland, Wyeth has now become the country's largest pharmaceutical employer.

▶ GLAXOSMITHKLINE TO ACQUIRE ID BIOMEDICAL

GlaxoSmithKline and ID Biomedical Corp. have signed a definitive agreement for GSK to acquire ID Biomedical, an integrated biotechnology company dedicated to the manufacturing and development of innovative vaccine products, including influenza vaccines. ID Biomedical has facilities in Canada and in the United States.

GSK's proposed acquisition of ID Biomedical reflects its continuing commitment to address the public health need for increased supply of influenza vaccines. ID Biomedical is currently in the process of expanding and upgrading its Canadian manufacturing facilities, which are expected, beginning in 2007, to produce around 75 million doses per year of ID Biomedical's Fluviral egg based influenza vaccine.

ID Biomedical will become a wholly owned subsidiary of GSK. The transaction is expected to close by the end of 2005 or early 2006.

GSK has moved quickly over the past few months to meet the growing demand for flu vaccines worldwide and to transform GSK into one of the leading global influenza vaccine manufacturers. In addition to acquiring an influenza vaccine business with sales to the Canadian public market, this transaction enhances GSK's vaccine presence in the United States where Fluarix, GSK's existing influenza vaccine, received FDA approval at the end of August. ID Biomedical's Fluviral has been granted fast track status by the FDA and is eligible for priority review.

"Combined with our recent investment to double influenza vaccine production capacity at our facility in Dresden, Germany, and our recent purchase of the Marietta vaccine site in Pennsylvania, where we will develop new flu vaccine production technology, the acquisition of ID Biomedical could also represent a major step in GSK's approach against pandemic flu threat," says Jean Stephenne, president of GSK Biologicals, the vaccines division of GSK. "GSK also is developing an improved flu vaccine for the elderly."

In the next five years, GSK hopes to launch five major new vaccines: an HPV vaccine targeting cervical cancer, a vaccine against rotavirus (already approved in 13 countries including Mexico), a vaccine to prevent pneumococcal disease, an improved flu vaccine for the elderly, and a meningitis combination vaccine for infants in the Unite States.

The proposed acquisition also brings other selected candidate vaccines under development by ID Biomedical, FluINsure (an intranasal influenza vaccine), StreptAvax (an injectable group A Streptococcus vaccine), PGCvax (a Streptococcus pneumonia vaccine), into GSK Biologicals vaccine pipeline, which is already extremely rich and well balanced.

Source: Wyeth Pharmaceuticals, Collegeville, Pa. For more information, visit wyeth.com. GlaxoSmithKline Biologicals, Belgium. For more information, visit gsk.com.

BIOTECH — BEYOND BORDERS 2005

COMING OF AGE

The U.S. biotechnology sector is maturing rapidly, driven by a remarkable surge of new biotechnology products that started in **2003** and continued through **2004**. Capital markets are maturing, as well, in what promises to be a positive development for the sector.

PRODUCTS, PRODUCTS, PRODUCTS

The biotech industry's growth and maturation are driven by its product successes. Biotech companies now market about **230** drugs, including **13** therapeutic antibodies. The sector has an impressive pipeline of drugs in Phase III trials or awaiting regulatory approval. In **2004**, a new challenge emerged, as regulators increased their focus on product safety.

GLOBAL SOLUTIONS

Biotech hotbeds are emerging in the Asia-Pacific region, particularly Japan, India, and China. Korea and Singapore are creating niches in areas such as stem-cell research and manufacturing, helping the global industry meet challenges such as restrictive public policy and drug pricing pressures.

CAPITAL MARKETS

Biotech companies raised **$16.9** billion in capital in **2004** in the United States and **$3.4** billion in Europe, surpassing **2003** totals. Yet, the industry is challenged by disappointing IPO evaluations, and early-stage companies struggle to find the capital they need to thrive.

Source: Beyond Borders: Global Biotechnology Report 2005, Ernst & Young, New York.
For more information, visit ey.com.

EDSTROM. Funding financing activities has always been challenging for start-up companies. This will not change in 2006. The promise of the technology, time to market, and the quality of the management will make the difference. Access to risk capital and funding vehicles will be a challenge. The mood of the stock market will either facilitate or make these challenges greater.

FREIMAN. The development and regulatory challenges faced by small companies haven't really changed. Companies need experienced industry clinicians and regulatory people who are willing to put their hands in the "mud." Too frequently, people from big pharma can only work if surrounded by many colleagues. This is not the case in biotech. Selection of the right people is absolutely critical to any success.

MCGIRR. All companies that need to fund growth using equity from external sources — whether from an IPO or a follow-on offering — are always subject to the openness of the equity capital markets at any point in time. Even a strong company story won't play well when the markets are jittery; 2005 had some rough spots. Overall it looks like the markets might be calmer in 2006, although the lead up to midterm elections next fall could produce some ripples.

LAURIN. I predict that the funding/financing environment will remain difficult. We are fortunate to have the ability to deliver on both short-term revenue growth and have a very rich pipeline of products providing even greater growth potential. That mix seems to appeal to investors and has enabled us to finance our growth toward profitability. Everybody is competing for the same money. Projects that can attract financing must therefore combine many more criteria.

MCGIRR. One challenge to growing companies in the biotech/pharmaceutical and high-tech sectors in particular will be the fallout from adoption of FAS123R for fiscal years beginning after June 15, 2005. When the Financial Accounting Standards Board issued this new requirement, the intention — a good one — was to improve transparency for investors by reflecting the impact of equity awards made to employees on earnings. FAS123R is applicable to all forms of stock-based compensation (options, restricted stock, ESPP, and so on — except ESOPs). The requirement will impact GAAP numbers; and as a result, it is quite possible that it will be harder to determine underlying business performance. There are a number of assumptions that will go into each company's option pricing model to conform to the new requirements. Each company will make different judgments as they develop these company-specific assumptions, thus making it somewhat difficult to compare companies on an apples-to-apples basis. We are already hearing from analysts and investors that they will be trying to find easy ways to create pro forma financials without 123R calculations so that they can more easily assess how the business is progressing and compare one company with another.

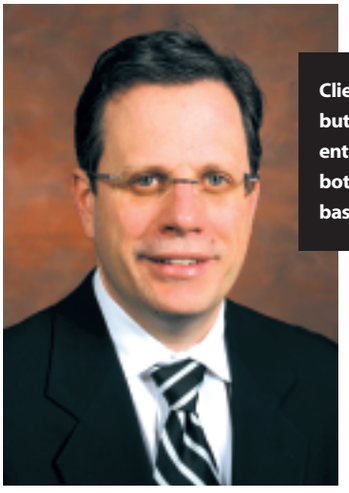
XANTHOPOULOS. Smaller and emerging companies will witness increasing emphasis of regulatory agencies toward drug safety and a growing emphasis from regulatory agencies for the use of biomarkers and surrogate endpoint use in drug development. Naturally, much of this oversight will accelerate costs in drug development and add to the time it now takes to bring drugs to market. Likewise, smaller and emerging public companies will continue to struggle with the costs and compliance issues. In June 2005, we entered into a global license and codevelopment agreement with Novartis to develop and commercialize ANA975 and additional Toll-like Receptor 7 oral prodrugs for chronic hepatitis C virus and hepatitis B virus, as well as other infectious disease indications. This agreement, which has a potential value of $570 million, $30 million of which we've already received, has transformed the company and taken it to a new level in its five-year history. We are now looking at and looking for strategic partnerships and in-licensing deals that strengthen our clinical development pipeline and enhance the long-term vision of the company, which is to become a fully integrated biopharmaceutical company.

GESSLER. In 2006, smaller and emerging companies in the industry are likely to face continued competition for funding, investor demand for effective allocation of resources, necessary broadening of their business portfolios, and the need to attract and, more importantly, retain top talent. Our industry remains a challenge for the vast majority of participants. And yet, it is Darwinian in nature, in that the best adapted survive.

GREENLEAF. In terms of development, smaller companies will continue to be challenged by how their development partners prioritize the clinical trials. There are many competing trials in the United States. Orga-

HAKAN EDSTROM
MannKind

Financing has always been challenging for start-up companies. This will not change in 2006. The promise of the technology, time to market, and the quality of the management will make the difference.



Client partnerships can be energizing and rewarding but require tireless perseverance, determination, enthusiasm about working together, and ultimately both parties remaining committed to delivering the basic premise upon which the partnership is based.

MARK GESSLER
Gene Logic

DAVID MCGIRR
Cubist Pharmaceuticals

All companies that need to fund growth using equity from external sources — whether for an IPO or a follow-on offering — are always subject to the openness of the equity capital markets at any point in time.

DANIEL GREENLEAF
VioQuest

In terms of development, smaller companies will continue to be challenged by how their development partners prioritize the clinical trials. Organizations will have to manage this process very closely, or time lines will slip.

DR. KLEANTHIS XANTHOPOULOS
Anadys Pharmaceuticals

Smaller and emerging companies will see increasing emphasis from agencies toward drug safety and a growing emphasis from regulatory agencies for the use of biomarkers and surrogate endpoint use in drug development.

nizations will have to manage this process very closely or time lines will slip. Expertise in protocol feasibility and regulatory understanding is in high demand because of the dearth of broad expertise in the industry. Companies need to seek the best personnel they can find in these areas. We also will continue to look for targeted oncology products that have either an assay associated with the identification of the patient or one that has a known biomarkers so that an assay could be developed to target the patients. VioQuest also will seek clinical partners outside the United States because of their proven ability to accrue patients, run high quality trials, and deliver on milestones. In other words, better alignment and fewer competing studies.

GESSLER. Client partnerships can be energizing and rewarding but require tireless perseverance, determination, enthusiasm about working together, and ultimately both parties remaining committed to delivering the basic premise upon which the partnership is based. Generally speaking, our strategy is to be flexible and creative in our approach to deals. To be maximally effective, we are avoiding cookie-cutter approaches. When we get into specific deal strategies, the answer for us is two-fold, because the goals of our genomics and drug repositioning businesses are somewhat different.

GENERIC DEFENSE STRATEGIES

In the next year alone, $11 billion in drug sales are expected to lose patent, with generic alternatives becoming available for at least 15 branded drugs. Experts discuss ways to protect their investments.

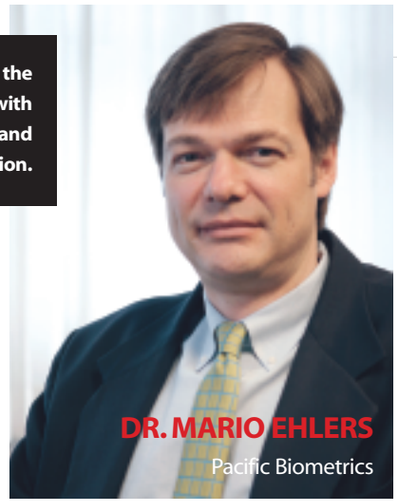
HESS. We've seen several key strategies emerge as being most effective, such as authorized generics. This is when a branded pharmaceutical company strikes an alliance with a generics manufacturer to produce a generic version of a certain product before patent expiration. By doing so, the pharmaceutical company begins to retain some market share for its product well ahead of patent expiration. There are pros and cons to the strategy. The company gives up some short-term revenue in exchange for royalty payments. In the long-term, however, the company prevents additional generic companies from eroding a large portion of its market share. Another strategy is next-generation products/evergreening. As patent expiration approaches, a brand team launches additional line extensions in the form of new formulations with additional dosing options. Launching additional line extensions has proven successful time and time again; so even when a generic version of the original formulation reaches the market, patients have already switched to more convenient dosing options of the branded product or a formulation that is easier to take than the original. The company may also opt to switch patients to a new product for the same indication. AstraZeneca's success in

switching Prilosec patients to Nexium before Prilosec's patent expiration is a prime example of generics defense through life-cycle management. There also is the over-the-counter (OTC) switching strategy. A pharmaceutical company brand team opts to sell its product over-the-counter (pending FDA approval) to compete with generic drugs' pricing. Advantages and disadvantages abound with OTC switching strategies. Companies can maintain much of their market share by competing with generic prices as an over-the-counter product. But the OTC price is often a fraction compared with what the price had been under patent, ensuring a dramatic drop in revenue once the product goes OTC. The key to generics defense is to develop an integrated, well-timed, life-cycle management strategy that adequately prepares the market for future line extensions that will maintain, or sometimes even grow, market share years after patent expiration.

GOLDSTONE. The expiration pace is increasing. And in 2006, the industry will experience the biggest patent expiry in its history, with $17 billion in sales of U.S. patents expiring. This follows on from $12 billion lost in 2002. The industry has a real problem, and generics companies can smell blood. The India-based generics industry will probably also become the Indian branded-drug industry. These companies have the technical expertise to reverse-engineer current branded drugs, so there's every reason to assume that Indian companies will at some point become leading developers of patented drugs. As China continues to evolve at a breathtaking pace, will herbal remedies continue to be the primary medical tool, or will a thirst for Western products and brands also carry over into Western remedies and drugs? Meanwhile Western medicine may be on its way to becoming more holistic, as it taps into the body's own mechanisms for healing itself rather than, for example, simply blocking a receptor.

EHLERS. A longer-term strategy for defense against generic attack is the emergence of targeted therapeutics. The coupling of drugs with specific companion diagnostics will create stronger IP positions and will present greater barriers to generic competition. Pharmaceutical companies need to continue to build the value proposition of innovative drugs, by supplanting older, one-size-fits-all drugs with newer targeted therapeutics that have substantially improved efficacy and safety profiles, even in therapeutic areas where effective, off-patent drugs are widely available.

A longer-term strategy for defense against generic attack is the emergence of targeted therapeutics. The coupling of drugs with specific companion diagnostics will create stronger IP positions and will present greater barriers to generic competition.



COMMUNICATIONS STRATEGIES

Industry leaders say successful communications depend on early actions across the board. Experts discuss what they believe are the most effective practices for communicating clinical-trial results to physicians, the managed-care community, investors, and consumers.

BARROSSE. Right now the industry is challenged to meet the public's expectations of transparency and good conduct in the drug safety area. The old tools — medical affairs and public relations — no longer have credibility in this area. Companies need to work on new leadership and R&D communication pro-

STUDY REVEALS $20 BILLION IN UNTAPPED GENERIC DRUG SAVINGS

The savings opportunity from increased use of generic medications has never been greater and will continue to surge, as more than $50 billion in sales of branded drugs will be exposed to generic competition with the loss of patent exclusivity over the next five years, according to a new report by Express Scripts Inc.

In the next year alone, **$11 billion** in drug sales are expected to lose patent, with generic alternatives becoming available for at least 15 branded drugs.

The largest-selling drug losing exclusivity in 2006 is Zocor, the cholesterol-reducing blockbuster that generated more than **$3 billion** in U.S. sales in 2004.

Despite the increasing availability of tools to encourage greater generic drug use, adoption varies. On average, a generic drug costs about **$60** less than a brand name drug. Consumers also pay a lower copayment for generic medications, saving $10 or more per prescription on average compared with branded medications.

Projectable to the U.S. commercially insured population, the study examined six major drug-therapy classes and was based on a random sample of about **3 million** individuals.

The Express Scripts Generic Drug Usage Report also ranked generic drug use and savings opportunities by state, revealing significant variation across the six drug categories used to treat common conditions such as stomach ulcers, inflammation, depression, high blood pressure, and high cholesterol.

The most dramatic savings potential exists for generic gastrointestinals, which are dispensed only **31%** nationwide but could feasibly reach as much as **95%** adoption, the report finds.

As such, greater use of nonbranded gastrointestinals alone could drive down costs an

GENERIC DRUG SAVINGS BY THERAPEUTIC CLASS

Therapy Class	Actual 2004	Generic Targets Generic Fill Rate	Potential Savings if Generic Usage Targets Reached
Gastrointestinals	31%	95%	$5.4 billion
Anticholesterol	7%	70%	$5.1 billion
Antidepressant	41%	75%	$3.2 billion
NSAIDs	47%	85%	$3.9 billion
Antihypertensives	48%	75%	$2.0 billion
Calcium channel blockers	43%	90%	$0.5 billion
TOTAL POTENTIAL SAVINGS			**$20 billion**

Source: 2004 Generic Drug Usage Report, Express Scripts Inc., St. Louis.
For more information, visit express-scripts.com.

MARK GOLDSTONE
Interbrand Wood

The pace of expiration is increasing. In 2006, we will see the biggest patent expiry in industry history, with $17 billion of U.S. patents expiring. This follows the $12 billion lost in 2002. The industry has a real problem, and generics companies can smell blood.

cesses to revitalize public perception of good stewardship in this area.

DURRANT. We believe in overcommunicating, for example, our studies are posted to clinicaltrials.gov. We welcome people to our Website and to engage with us at whatever level they feel comfortable with. We have an obligation to report findings — be they good, bad, or indifferent. This helps establish one of our foundation stones: trust. Whilst larger, better-resourced organizations may have formal alliance-management teams, we believe it is the job of everyone at PediaMed who may interact with a potential or current partner to adopt good alliance practices. There are textbooks filled with what these practices are. We believe that what are important are those principles congruent with our company core values. One of our strategies for growth is to become the preferred pediatrics partner. We have approached many companies over the last few years. What is gratifying is that people are now approaching us proactively to help them understand what it takes to successfully unlock the opportunities in pediatrics. This helps build another of our foundation stones: growth.

WOOD. The role and responsibility of pharmaceutical companies is coming under ever-greater scrutiny. Brands that have to be withdrawn — and the resulting lawsuits and litigation — may become an increasingly high-profile reality. Faced with the kind of

Steve Miller, M.D.
Express Scripts

As additional generics come to market and the use of prescription drugs grows, the opportunity to lower healthcare costs becomes even more significant.

additional $5.4 billion nationally.

In the anticholesterol category, generics are only dispensed **7%** of the time nationally. Drug costs could be reduced an additional $5.1 billion annually if generic fill rates (GFR) reach the **70%** goal projected in the report. The GFR goals used in the study are based on an evaluation of clinical efficacy and market dynamics of branded and generic medications.

"We have only scratched the surface in taking advantage of the money-saving potential of clinically sound generic drugs," says Steve Miller, M.D., VP of research at Express Scripts and a study author. "As additional generics come to market and the use of prescription drugs grows, the opportunity to lower healthcare costs becomes even more significant. Best of all, using more generics simply requires better education and awareness of alternatives, not a big-dollar, up-front investment. Consider that **$20 billion** in generic drug savings in just six therapy classes is the same amount America's community hospitals spend each year on uncompensated care for the uninsured."

KEY FINDINGS — ACROSS THERAPIES

▶ **THE ESTIMATED ANNUAL SAVINGS** opportunity among commercially insured members across the 48 states and six therapy classes evaluated was more than $20 billion.

▶ **THE GREATEST SAVINGS** opportunity comes from increased use of generics in the gastrointestinal therapy class where reaching generic targets would save employers, state governments, and members more than $5 billion annually.

▶ **SIGNIFICANT SAVINGS** in the antihyperlipidemic therapy class are also noted, where savings of more than $5 billion could be realized if states were able to reach the GFR opportunity of 70%.

KEY FINDINGS — ACROSS STATES

▶ **THE OVERALL GFR** in 2004 varied from a low of 41% in New Jersey, to a high of 56% in Oregon, Massachusetts, and New Mexico.

▶ **MASSACHUSETTS HAD THE HIGHEST GFR** for three of the six therapy classes (antihypertensives, antidepressants, and gastrointestinals) and New Jersey had the lowest GFR for four of the six therapy classes evaluated (antihypertensives, antidepressants, calcium channel blockers, and lipid lowering).

▶ **STATES WITH THE LARGEST SAVINGS OPPORTUNITY** include California, Texas, Florida, New York, Ohio, and Pennsylvania, each with the potential to save more than $1 billion annually in prescription-drug costs for employers, government agencies, and state residents.

KEY FINDINGS — ACROSS STAKEHOLDERS

▶ **A RECOGNITION** that using more generic drugs will free up resources to meet other pressing healthcare needs and help preserve the pharmacy benefit — without impacting quality

▶ **INCREASED AWARENESS** of generic alternatives to brand drugs by patients and physicians

▶ **ADOPTION OF PHARMACY BENEFIT-PLAN** designs that encourage greater use of generic drugs; for example, a program called step therapy, where a generic drug is tried first, before a brand

▶ **ENACTMENT OF STATE LAWS** and regulations that promote the use of chemically equivalent generic alternatives to brand drugs

Note: Express Scripts' clinical pharmacists estimated the therapy class generic targets by evaluating the clinical efficacy and market dynamics of branded and generic medications across 10 of the top therapy classes.
Source: 2004 Generic Drug Usage Report, Express Scripts Inc., St. Louis.
For more information, visit express-scripts.com.

BIOGENERICS: AN EMERGING GLOBAL MARKET

There are potentially big rewards for companies that can overcome the regulatory, legal, and technical obstacles related to biogenerics.

- **BIOLOGICAL DRUGS ACCOUNT FOR 10% TO 15%** of the world pharmaceutical market. This is equal to about $30 billion in the United States alone. The biologicals sector is outperforming the pharmaceutical industry as a whole, growing at double the pace in some cases. But the development of the biogenerics sector will only come after some significant problems have been tackled.
- **BIOLOGIC DRUGS ARE EXPENSIVE AND INCREASINGLY WIDELY USED**. For chemical drugs, generic versions of off-patent products have helped to reduce pharmacy bills and increase funding for new products. It would seem obvious, therefore, for companies to develop generic versions of the older biologic drugs and for health payers to welcome them. But achieving this has proved far from straightforward.
- **EARLY MARKET ENTRY IN THE UNITED STATES IS NOT A PRACTICAL PROPOSITION.** The nature of the current regulatory system precludes approval in most cases. The FDA has yet to issue detailed guidance on the topic, although this is planned for 2005. Only then can Congress begin the legislative process. Given the time this will probably take, biogenerics are unlikely to appear on the U.S. market until at least 2010.
- **THE EUROPEAN UNION IS SOME YEARS AHEAD OF THE UNITED STATES**, on paper at least. The 2003 EU regulatory reforms make specific provision for biogenerics, and the EMEA has issued guidance documents on most of the major products. No product has yet been approved in the European Union, but a number of companies are still preparing regulatory submissions. Market entry in two to three years is a realistic prospect.

Source: Espicom Business Intelligence, West Sussex, United Kingdom. For more information, visit espicom.com.\

heat it has endured in the last several years, the pharma industry has to start to stand up and defend itself by communicating with all of its audiences about the economic and risk/benefit realities of the business. This is an industry trying to do good things under extremely difficult circumstances, and, as with any business, it is entitled to profit so that it can continue to try to do more good things. A much greater degree of transparency and openness in communication is needed. How individual companies and the industry as a whole deal with these realities is a big question. This also extends to social responsibility — from malaria to AIDS in Africa to bird flu pandemics and the lack of vaccines to drug pricing, which is and will continue to be a highly charged social and political issue throughout the world and is an issue that the U.S. government may feel compelled to interfere with at some point in time.

VAN DEUSEN. Publication planning is fundamental to effective brand communication. As we look to 2006, we see publication planning — a comprehensive guide for the proper strategy, management, and communication of clinical data to healthcare professionals — taking on even greater significance as pharmaceutical companies look to accelerate the adoption and recommendation of their drugs and devices in a changing environment. Provoked by calls for more transparency in the drug-development process, an increasing number of medical journals now require that extensive information on clinical trials be made available on databases accessible to the public before they will consider a trial for publication. Another important consequence is that clinical trials need to be submitted for publication within one year of completion. Overworked investigators and overstretched clinical-development teams will only meet this deadline if they are supported by skilled medical writers and editors who can quickly prepare objective manuscripts suitable for an appropriately chosen medical journal and by an integrated project-management team that

MORE THAN 40 MAJOR PATENTS EXPIRE AND DRIVE GROWTH TO 2009

Up to $60 billion of major branded drugs sales are at risk from new generics competition between now and 2009, which is fueling growth of specialist generic pharmaceutical companies, according to a report from Urch Publishing.

Generic Competition to 2009 — The impact of patent expirations on sales of major drugs reports that up to **$60 billion of revenue currently generated in Europe and the United States** by big pharmaceutical companies could come under threat as patents expire and generic competition kicks in.

The impact of these expirations is not equally spread among the big pharmaceutical companies.

According to the report, **there is a considerable difference between the top 20 pharmaceutical companies** in both the number of products and the amount of revenue under threat from the potential introduction of generics. Eli Lilly, Schering-Plough, Bayer, Amgen, and Schering AG have little or no threat under current legislation, while GlaxoSmithKline, Pfizer, and Roche are the most exposed to generic threats in the period 2005 to 2009.

The beneficiaries of this growth are likely to be the major generics companies, in particular Sandoz and Teva. **The leading generics companies are** likely to remain those based in Europe — especially Germany — and North America, plus those in Israel and India. The near term may also witness the emergence of new players from the Far East, especially China and Korea, taking advantage of low cost bases and scientific capabilities.

In **2004 global sales of generic products** were reported to be **$58 billion**, accounting for 14% of the global healthcare market. The five-year period to 2009 could witness **$15 billion to $20 billion of additional revenue** generated by the generics companies, significantly enhancing their growth prospects.

Source: Urch Publishing Ltd., London.
For more information, visit urchpublishing.com/publications/general.

Implementing an internal communications strategy is as crucial — if not more so — as placing corporate-awareness ads in the media. Before we can fix our reputation externally, we need to first look to ourselves.

Providing evidence of value is not the issue. People know how valuable drugs are. They don't question that. The sticking point is the high costs for drugs, which prevent access for so many people.

HARRY SWEENEY
Dorland

helps the authors and contributors through the review process to meet the deadline. Against the current backdrop of drug withdrawals from the marketplace, consumer and prescriber skepticism has diminished the return on DTC advertising, and the influence of costly armies of sales representatives is steadily declining as too many reps struggle to see doctors with less and less time for them. Publications in peer-reviewed journals, however, will continue to be credible and highly valued sources of information for busy prescribers. At a time when new drug development costs are reaching an estimated $800 million, when effective patent life is diminishing, and when other communication channels are simply not working as well as they used to, the impact of an intelligent and well-executed publication plan has never been more critical to subsequent communications and a company's bottom line.

INDUSTRY VALUE AND PUBLIC RELATIONS

Some experts say the ongoing challenge for the pharmaceutical sector will be to determine how much transparency and evidence around value are necessary to regain the public's trust. Industry leaders discuss what the pharmaceutical industry as a whole — as well as individual companies — need to do in the next 12 to 24 months to address the perception of the industry.

Publication planning is fundamental to effective brand communication. As we look to 2006, we see publication planning taking on even greater significance as companies look to accelerate the adoption and recommendation of their drugs in a changing environment.

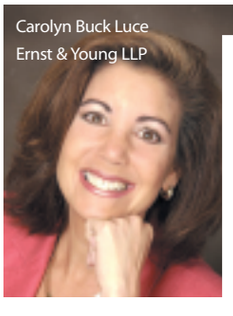
GLENN VAN DEUSEN
Parexel International

MARITA GOMEZ
HealthInfo Direct

SWEENEY. Providing evidence of value is not the issue; people know how valuable drugs are, they don't question that. The sticking point is the high cost of drugs, which prevents access for so many people. The public wants, and deserves, answers that will provide short-term solutions to access. The public does not link the value of drugs to the slowing down of medical inflation. That is discussion for economists; it is not relevant to the public. I have three suggestions for what the pharmaceutical industry needs to do. First, engagement: talk to consumers on their own turf, where they live, through grassroots efforts. Second, transparency: don't double talk, leave

SAFEGUARDING THE PHARMACEUTICAL SUPPLY CHAIN AND DEMONSTRATING TRANSPARENCY SEEN AS CRITICAL TO BUILDING PUBLIC CONFIDENCE AND MANAGING BUSINESS RISKS

In 2005, pharmaceutical companies are taking unprecedented actions to regain the public's trust.



Carolyn Buck Luce
Ernst & Young LLP

We see examples of pharmaceutical companies taking significant strides to gain public trust in this sector.

According to the third annual Progressions 2005: The Ernst & Young Global Pharmaceutical Report, companies are taking unprecedented actions to regain the public's trust by engaging in an open dialogue around drug-safety issues and drug-promotional objectives, while renewing their focus on demonstrating value through medicines.

"To build confidence, companies are grappling with how they ensure the integrity of their supply chain, to mitigate regulatory risks through greater transparency, and ultimately build awareness of the value and positive role they play in improving people's lives and reducing the cost of disease," says Carolyn Buck Luce, Leader, Metro New York Pharmaceutical Sector, Ernst & Young LLP.

According to Ernst & Young's report, the industry is elevating its focus on global supply-chain integrity, regulatory risk management, and industry value.

Source: Ernst & Young, New York.
For more information, visit ey.com.

JOHN RHODES
Deloitte

One of the challenges that is the most difficult to address is how to increase the understanding about the value of what might be the largest out-of-pocket expenditure but the smallest in the grand scheme of overall healthcare supply costs.

AMANDA RHODES
MicroMass

Facing enhanced public scrutiny, tighter government regulations, stricter managed-care guidelines, and increasingly information-savvy consumers, pharmaceutical brands need to find more nuanced, targeted ways of building deep, trusting, and long-lasting relationships with stakeholders.

the lawyers out of it, and talk to the public about the topics that interest and concern them. And three, candor: tell them what can be fixed and by whom. There are so many players in the healthcare game that it is important to identify how to solve the problems that can be solved with doctors, allied health professionals, managed-care organizations, pharmacy benefit managers, employers, and so on — the list is endless. Be honest about what cannot be fixed, and identify the timing to put appropriate fixes in place.

A. RHODES. Facing enhanced public scrutiny, tighter government regulations, stricter managed-care guidelines, and increasingly information-savvy consumers, pharmaceutical brands need to find more nuanced, targeted ways to build deep, trusting, and long-lasting relationships with stakeholders. Relationship marketing is an excellent way for pharmaceutical companies to establish positive and ongoing, communication with these stakeholders, especially consumers who rely on the industry's products. Relationship programs help brands increase their stakeholders' affinity for the pharmaceutical company while also increasing stakeholder loyalty to their brands. And by impacting medication adherence, relationship marketing

MEDIA COVERAGE OF PRESCRIPTION DRUG RECALLS AND RECENT LAWSUIT JUDGMENTS MAY HAVE NEGATIVE IMPACT ON CLINICAL-TRIAL PARTICIPATION

The heightened awareness of safety issues with certain drugs may cause Americans to be more hesitant about participating in a broad range of clinical studies.

According to a nationwide survey by The Center for Information and Study on Clinical Research Participation (CISCRP) and Opinion Dynamics Corporation (ODC), 48% of survey respondents say they would be less likely to take part in a clinical trial given recent media coverage on the safety of certain prescription drugs, and four out of 10 (41%) say they would be less likely to participate because of recent lawsuit judgments against a drug company. Despite these new findings, the majority of respondents (67%) believe that clinical-research studies are safe or somewhat safe, which is virtually identical to numbers reported in the CISCRP/ODC December 2004 survey.

"Clinical-research participation is crucial to the advancement of medical science," says Roni Thaler, president and cofounder of CISCRP. "Recent news coverage in the media may be having a profound and broad impact on public perception, but the reality is that the public has little education. It is important that the public better understand the clinical research process so that people can make an informed decision about their own participation."

The survey of 1,000 adults, the second in a series by CISCRP and ODC, was conducted to gain insight into public perceptions about clinical research following the media attention over the last nine months regarding the safety of several prescription medications.

The survey also showed that 51% of Americans approve of the job the FDA is doing to protect the health and safety of Americans as it relates to the development and monitoring of new drugs. Of the remaining 49% of respondents, 36% said they disapproved and 13% were unsure. There was a notable disparity among participants under the age of 30 versus those over 65 years old. Sixty-four percent of 30-and-under survey participants approved of the FDA's track record, while only 36% of the 65+ respondents expressed approval. Only 19% of those 30 and under disapprove, while 43% of those 65 or older disapprove.

Roni Thaler
Opinion Dynamics

Richard Greif
Opinion Dynamics

It is important that the public better understand the clinical-research process so that people can make an informed decision about their own participation.

The heightened awareness of safety issues with certain drugs may cause Americans to be more hesitant about participating in a broad range of clinical studies, thereby impacting the process of developing new treatments overall.

"The heightened awareness of safety issues with certain drugs may cause Americans to be more hesitant about participating in a broad range of clinical studies, thereby impacting the process of developing new treatments overall," says Richard Greif, project director at ODC.

Source: The Center for Information and Study on Clinical Research Participation (CISCRP), Boston. For more information, visit smartparticipant.org. Opinion Dynamics Corp., Cambridge, Mass. For more information, visit opiniondynamics.com.

improves quality of life for the patient. As with any relationship, relationship marketing can be challenging and full of pitfalls; but when done well, the return is worth the investment, for both sponsor and recipient.

GOMEZ. In 2005, pharma executives publicly acknowledged that corporate reputation was crucial to their company's bottom line. In the same breath, they announced their commitment to altering the negative perception. While many have placed their money where their mouths are, which I applaud, some forgot to share the news with everyone within their companies. As a result, confusion has ensued; skepticism and poorly placed marketing tactics have erupted. Most corporate executives say their company's reputation speaks volumes, yet few set up an internal communication strategy to ensure that they consistently deliver the message. There are several things executives can do, which I call Operation Reputation: Rebuilding Internally. First, involve corporate/investor PR, human resources, and customer service. Don't allow marketing or the outside agency to develop and implement tactics without first soliciting insight from these groups. Next, implement a consistent message. What is said internally should be consistent with what is said externally. Otherwise, the management team will be viewed as "a do as I say, not as I do" management. And then apply communication processes. There are those internally who are afraid to talk with key customers because they don't know what to say. A corporate communications process provides staff with guidance on how to build and apply tactics that support the corporate objective. Also, recognize individuals who helped share positive stories about the company's impact on patients' lives, for example the company's efforts to send needed medicines to third-world countries. They become role models for others, and their stories reaffirm the company's commitment to all. Finally, measure staff views of the company internally before and after PR tactics are applied. Also compare these data with data from customers to determine if there are any inconsistencies. Implementing an internal communication strategy is as crucial — if not more so — as placing corporate awareness ads in the media. Before we can fix our reputation externally, we need to first look to ourselves.

U.S. ADULTS STRONGLY FAVOR AND VALUE NEW MEDICAL TECHNOLOGIES IN THEIR DOCTOR'S OFFICES

While only a minority of U.S. adults have experience with new medical technologies, such as electronic medical records and digital imaging equipment in their doctor's offices, vast majorities are in favor of having their doctors adopt new technologies in their practices, according to a Wall Street Journal Online/Harris Interactive Health-Care Poll.

Furthermore, a large number of adults believe new medical technologies will either reduce the costs of medical care or are worth the investment because they will improve the quality of care.

SUPPORT FOR THE USE OF IMAGING TO PROTECT PATIENT PRIVACY

	ALL ADULTS	GENDER MALE	GENDER FEMALE
Favor strongly/somewhat (NET)	71%	76%	66%
Strongly favor	33%	36%	29%
Favor somewhat	38%	39%	37%
Oppose strongly/somewhat (NET)	15%	13%	17%
Oppose somewhat	9%	8%	10%
Strongly oppose	6%	5%	7%
Not sure	14%	12%	17%

Note: Percentages may not add up to 100% because of rounding.

PERCEPTIONS OF THE VALUE OF NEW MEDICAL TECHNOLOGIES

Which one of the following statements do you tend to agree with most?

	ALL ADULTS	GENDER MALE	GENDER FEMALE
New technologies such as electronic medical records and digital-imaging devices are worth the money they cost because they will improve patient care.	31%	33%	30%
New technologies such as electronic medical records and digital-imaging devices cost more money than they are worth.	10%	10%	11%
New technologies such as electronic medical records and digital-imaging devices will ultimately reduce the costs of medical care.	36%	40%	31%
Not sure	23%	17%	28%

Note 1: Single-response question.
Note 2: Percentages may not add up to 100% due to rounding.

EXPERIENCE WITH NEW MEDICAL TECHNOLOGIES

Relatively small numbers of U.S. adults report that their doctor has ever used some new technologies for them or a member of their family during a doctor visit or to provide or discuss follow-up treatment.

SPECIFICALLY

16% REPORT THAT THEIR DOCTOR has used an electronic medical record to capture their medical information.

14% SAY THEIR DOCTOR has used a personal digital device such as a Palm Pilot or a hand-held computer to record their information.

8% REPORT THAT THEIR DOCTOR has used e-mail to communicate directly with them or their family members, while an equal percentage report that their doctors have used digital imaging equipment that allows the doctor to send pictures or other images via e-mail (8%).

5% HAVE EXPERIENCE WITH a home monitoring device that allowed them to send medical information, such as blood pressure readings or blood tests, to their doctor's offices via the telephone or e-mail.

SUPPORT FOR THE ADOPTION OF NEW MEDICAL TECHNOLOGIES

Despite limited personal experience with these new medical technologies, at least three-quarters of adults strongly or somewhat favor having their doctors use these types of new technologies when caring for them or their family members. Adults most strongly favor the use of home-monitoring devices (**83%** strongly or somewhat favor), followed closely by e-mail for doctors and patients to communicate

DR. CAMERON DURRANT
PediaMed

Industry leaders say the value of the health-sciences industry to regional economies is becoming better understood, but the ongoing challenge for the pharmaceutical sector will be to determine how much transparency and evidence around value are necessary to regain the public's trust.

DURRANT. Corporate reputation starts with the people in the company. We hire to rigorous standards and search for people of character who will find resonance in our core company values. We adopt a consistent process to find people with a strong work ethic, who are smart and open to true development. Establishing a clear vision and corporate brand is obviously vital. Leveraging communication channels to articulate the corporate positioning requires a relentless discipline. If we are then able to deliver on the promise, we believe we can create and grow value. Building value is another foundation stone.

J. RHODES. The industry has launched recent campaigns to better convey what it does for patients. One of the challenges that is the most difficult to address is how to increase the understanding about the value of what might be the largest out-of-pocket expenditure but the smallest in the grand scheme of overall healthcare supply costs. The industry will need to find the right messaging around this issue without running the danger of harmful reactions against other providers in the overall healthcare supply chain. Bottom line is: communicate clearly and openly, and continue to emphasize the potential benefits of some of the potential therapies in the discovery stage. There are a large number of very difficult-to-treat illnesses that companies need to pursue, and a hostile healthcare environment is not in the best interest of the discovery of future medicines. Additionally, I think manufacturers and the U.S. government could take a very proactive role in restoring a vibrant vaccines business in the United States to work toward the prevention

SUPPORT FOR THE ADOPTION OF NEW MEDICAL TECHNOLOGIES

Based on what you know or have heard, how do you feel about having your doctor(s) use these types of new technologies when caring for you or a family member?

	Favor Strongly/ Somewhat (NET)	Strongly Favor	Favor Somewhat	Oppose Strongly/ Somewhat (NET)	Oppose Somewhat	Strongly Oppose	Not Sure
An electronic medical record to capture medical information	78%	42%	36%	9%	5%	5%	13%
E-mail to communicate directly with you or a family member	81%	49%	32%	9%	4%	5%	10%
A personal digital device such as a Palm Pilot or a hand-held computer to record information	75%	37%	38%	11%	7%	4%	14%
Digital-imaging equipment that allows the doctor to send pictures or other images via e-mail	78%	44%	34%	9%	5%	3%	13%
A home-monitoring device that allows you to send medical information – like blood-pressure readings or blood tests – to the doctor's office via the telephone or e-mail	83%	51%	33%	5%	3%	3%	11%

Note: Percentages may not add up to 100% because of rounding.

EXPERIENCE WITH NEW MEDICAL TECHNOLOGIES

Which of the following new technologies, if any, has a doctor ever used for you or a member of your family during a doctor visit or to provide or discuss follow-up treatment?

	All Adults	Gender Male	Gender Female
An electronic medical record to capture medical information	16%	15%	16%
A personal digital device like a Palm Pilot or a hand-held computer to record information	14%	15%	13%
E-mail to communicate directly with you or a family member	8%	8%	8%
Digital-imaging equipment that allows the doctor to send pictures or other images via e-mail	8%	9%	7%
A home-monitoring device that allows you to send medical information – such as blood-pressure readings or blood tests – to the doctor's office via the telephone or e-mail	5%	6%	5%
None of these	55%	53%	57%
Not sure	12%	13%	10%

Note: Multiple-response question.

directly (**81%**), electronic medical records (**78%**), digital-imaging equipment (**78%**), and personal digital devices to record information (**75%**).

Considerable support also exists for new technology being developed that uses internal imaging to capture characteristics of a human's internal anatomy, such as veins in the palm of the hand, to confirm identity. About seven in 10 (**71%**) adults would strongly or somewhat favor using this type of technology to help protect patients' medical records, for example to restrict release or use of medical records without such verification.

THE VALUE OF NEW MEDICAL TECHNOLOGIES

The majority of adults do believe these new medical technologies provide value; nearly one-third (**31%**) believe new technologies such as electronic medical records and digital imaging devices are worth the money they cost because they will improve patient care, and **36%** believe these new technologies will ultimately reduce the costs of medical care. Only one in 10 (**10%**) believes these new technologies cost more money than they are worth, and a further **23%** are not sure.

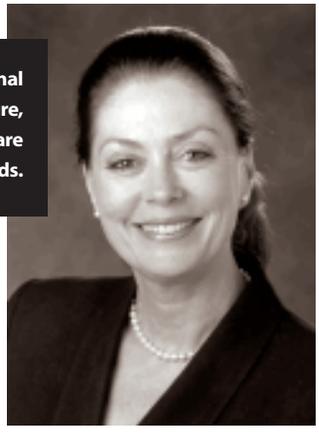
Source: Harris Interactive Inc., Rochester, N.Y.
For more information, visit harrisinteractive.com.

Technology has evolved to the point that it facilitates new processes that allow for a more strategic approach to the management of individual trials and portfolios of compounds.

GLEN DE VRIES
Medidata Solutions

As the U.S. healthcare industry moves closer to a national implementation of an electronic health information infrastructure, pharmaceutical companies will begin investing in more healthcare information technologies and standards.

MOLLIE SHIELDS-UEHLING
SAFE-BioPharma



of broad-based health emergencies. The industry could very quickly improve its image by investing in this area.

EHLERS. A long-term strategy for regaining the public trust is a clear commitment to enhancing the safety and efficacy of innovator drugs. Indiscriminate direct-to-consumer advertising and prescribing of one-size-fits-all blockbuster drugs is inappropriate, results in an unacceptable incidence of adverse events and lack of efficacy, and leads to suspicions of pharma-company greed. A commitment to true targeted therapeutics ushers in a new era in which genuine attempts are made to match the therapy to the patient, eventually culminating in true personalized medicine.

▶ TECHNOLOGY

Worldwide IT spending for the life-sciences sector will reach $38.9 billion in 2008, driven by the need to tackle industry pain points, such as regulatory burdens and costly clinical trials, and by life-sciences companies leveraging IT to enable personalized medicine.

DE VRIES. Pharmaceutical companies are under a variety of pressures — market pressure, regulatory/safety pressure, consumer pricing pressure, and capacity pressure — on both a domestic and global level. Both large and small sponsors are faced with challenges of scalability in development to address financial pressures and maximize throughput in the clinical-trial process. Technology has evolved to the point that it facilitates new processes that allow for a more strategic approach to the management of individual trials and portfolios of compounds. These new technologies can provide earlier visibility into critical data that can enhance scientific processes but also provide the information necessary to streamline decision-making around the deployment of financial and human resources across trials to maximize global efficiency.

SHIELDS-UEHLING. As the U.S. healthcare industry moves closer to a national implementation of an electronic health-information infrastructure, pharmaceutical companies will begin investing in more healthcare-information technologies and standards. SAFE (Secure Access For Everyone) is an integral component of the global e-health movement and is the only global standard for the healthcare community that enables trusted, secure, legally enforceable, paperless business and clinical transactions. The adoption of technology standards, such as SAFE, is a critical aspect of the national health information technology strategy because it ensures the secure exchange of electronic clinical-research data and other electronic healthcare transactions. Government agencies, including the FDA, are seeking greater use of electronic processes for delivery of high-quality healthcare to patients and for regulatory submissions. SAFE is the biopharmaceutical industry's initiative for improving industry processes and industry-to-regulator processes. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

SOFTWARE LEADS AS FASTEST GROWING IT SPENDING CATEGORY FOR LIFE-SCIENCES COMPANIES

Worldwide IT spending for the life-sciences sector will reach $38.9 billion in 2008.

This growth will be driven by the need to tackle industry pain points, such as regulatory burdens and costly clinical trials, and by life-sciences companies leveraging IT to enable personalized medicine, according to Life Science Insights (LSI), an IDC Company.

Life-science companies are pouring significant resources into applications that help them act intelligently on the massive quantities of data generated within their organizations.

Life-sciences companies are pouring significant resources into applications that help them act intelligently on the massive quantities of data generated within their organizations. Additionally, they are optimizing the operation of their hardware investments through infrastructure software investments. Significant improvements in certain industry-specific software categories, such as CTMS, also are encouraging some companies to migrate from internally developed systems to off-the-shelf solutions.

According to the market model, investments in hardware also are expected to exceed average IT market growth rates, as information infrastructure needs remain a top priority among life-sciences companies. Network equipment also is a strong growth hardware category as life-sciences companies increase the transmission capacities of their networks to accommodate the ever-increasing volumes of data generated and the growing need for real-time collaboration across departments, functional areas, physical sites, and geographies.

Source: Life Science Insights, an IDC Company, Framingham, Mass. For more information, visit lifescience-insights.com.