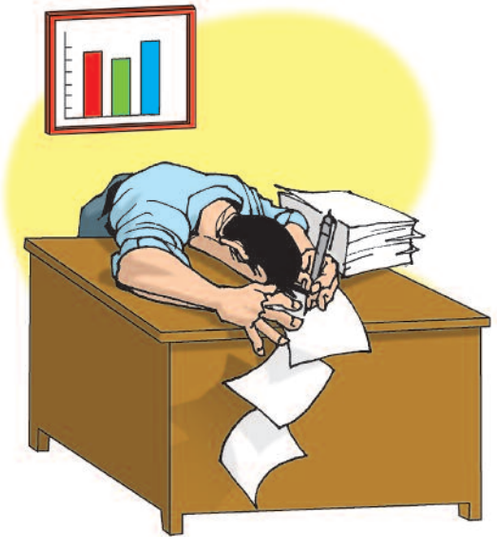
PHARMA TRAX

SALES, MARKETING, AND R&D TRENDS AFFECTING THE HEALTHCARE INDUSTRY



Clarity of Strategy Crucial to **PHARMA LICENSING SUCCESS**

Pharmaceutical firms looking to license new drug candidates from other firms will improve their chances of achieving a successful alliance if they focus on building a relationship, not just acquiring an asset, according to a panel of drug industry leaders recently convened by the Tufts Center for the Study of Drug Development (CSDD).

The executives also agreed that the more adept each party is at clearly defining its strategy, the better able they will be to attract the right potential partnering opportunities, while saving time and effort pursuing opportunities that won't pan out.

"While there is no single approach to licensing, senior managers in the research-based drug industry understand that the factors defining success in drug development are rapidly changing," notes Tufts CSDD Director Kenneth Kaitin. "For example, developing a product considered best or first in its class is becoming secondary to marketing exclusivity, which may do more to drive revenue."

For more information, visit csdd.tufts.edu

Personalized Medicine and the **PAYOFF FOR DIAGNOSTIC COMPANIES**

Pharmaceutical and molecular test product combinations, known as pharmacodiagnostics, are seen as the pathway to personalized medicine, which is expected to foster earlier detection of disease, and a reduction in healthcare costs and adverse drug reactions.

The market for pharmacodiagnostics is estimated to be at $68 million in 2009 but will likely grow to $140 million by 2013, according to a recent report from Kalorama Information.

Personalized medicine can improve healthcare and reap large profits for diagnostic companies, but it may require new business models. According to Kalorama's Pharmacodiagnostics and Personalized Medicine 2009, one challenge presented by personalized medicine is how to compensate testing companies.

Given the traditional diagnostic business model, Kalorama believes that there may not be enough dollars to make the enterprise profitable, no matter how popular the concept is. Even if all patients with cancer are screened with these tests — a highly unlikely event, according to Kalorama researchers — the company would see a smaller potential market than most expect, perhaps $800 million by 2015, compared with the nearly $5 billion in-vitro cancer diagnostics industry. This market may not produce the incentives needed for investment in test development.

"Everyone wants to make personalized medicine happen," says Kalorama Publisher Bruce Carlson. "But if you want to unlock the entrepreneurial spirit to make personalized medicine a broad reality across disease categories, the payoff question needs to be addressed. Either reimbursement rates will have to be increased, or test makers will have to seek royalties on sales of the end pharmaceutical for which they develop the test, or both."

For more information, visit kaloramainformation.com.

CHINA REMAINS PROMISING MARKET Despite Global Pharma Challenges

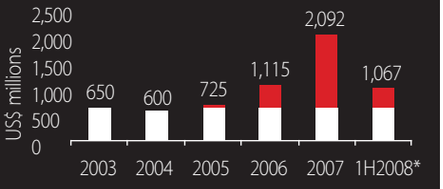
China is now among the top five in worldwide drug markets in terms of overall size. Although current market conditions are uncertain, a recent PricewaterhouseCoopers (PwC) report projects pharmaceutical sales in China will grow at a double-digit rate, reaching $28.3 billion by 2010.

Mike Keech

Given the tremendous growth in this market along with continuing pressure to control costs, pharma multinationals have ample opportunity to expand by investing in China, says Michael Keech.

According to the second edition of PwC's report, Investing in China's Pharmaceutical Industry, rising per-capita drug expenditures, supported by strong economic growth, will further feed market gains in China. Although there are challenges to overcome, the rewards of cost benefits and a growing market are continuous and consistent drivers for investment in the Chinese pharmaceutical industry, the report says.

CHINA DISCLOSED M&A DEALS



*First half of 2008

Source: Asian Venture Capital, as published by PricewaterhouseCoopers, Investing in China's Pharmaceutical Industry – 2nd Edition. For more information, visit pwc.com/pharma.

According to the report, fast-growing pharma sectors within China include contract research organizations and manufacturing organizations, where double-digit growth is expected to continue in the coming years. Intellectual property protection has been a major concern for foreign companies operating in China. But recent developments have influenced the level of confidence of foreign firms in the protection of intellectual property in China, including an amendment to the Chinese Patent Law passed in December 2008 that strengthens patent law and increases the ceiling on monetary penalties for IP infringement.

"The opportunities in the pharmaceutical industry in China stretch far and wide," says Michael Keech, director, PricewaterhouseCoopers global pharmaceutical and life-sciences industry group. "Impending healthcare reform, the commitment to innovation by the Chinese government, and numerous tax incentives, among other things, are making China a much bigger player in the global pharmaceutical industry.

For more information, visit pwc.com/pharma.

PROPOSED FOLLOW-ON BIOLOGICS REGULATIONS Could Stifle Biotech Innovation

After years of ongoing debate, Congress has brought forward legislation based on the Hatch-Waxman Act of 1984 to create a regulatory pathway for the approval of follow-on biologics (FOBs), drugs envisioned as the biotechnology equivalent of generic drugs in the chemically based pharmaceutical industry.

Jim Hollingshead

Strong patent protections will likely be needed to attract the risk capital companies need, says Jim Hollingshead.

TOP RISKS FACING LIFE-SCIENCES COMPANIES

1. Demonstrating value and pricing pressures: Beginning early in the development process, companies can begin to measure and articulate the product's value, and open a dialogue with payers. Pipeline prioritization decisions can be made with a stronger consideration for a reimbursement pathway.
2. Capital access/capital allocation: Biotech companies are working to identify alternative sources of capital, while both the pharma and biotech industries are increasing emphasis on efficient capital allocation and managing the balance sheet.
3. Boosting R&D productivity: Pharma companies are beginning to emulate biotechs by breaking R&D into smaller, more innovative teams with greater autonomy.
4. Revolutionizing business models: Companies can adopt a portfolio approach, experimenting with different models to learn from other industries and explore new partnership models.
5. Ensuring safe products: To manage an increasingly complex global supply chain, companies should adopt a comprehensive risk management approach, plan early for post-marketing surveillance, and build strong relationships with customs authorities.
6. Protecting and capturing the value of intellectual property: The industry can increase advocacy on behalf of patent reform.
7. Sustaining a culture of innovation: Companies are exploring alternatives to the fully integrated R&D model that most pharma companies are built on.
8. Global supply chain integrity: Companies can improve due diligence of third-party suppliers, increase vigilance about regulations and standards in emerging markets, and employ more robust supply-chain management and internal controls.
9. Enabling access: With increased pressure to broaden access to therapies, companies can proactively define and execute a comprehensive approach in emerging markets, exploring creative pricing approaches and local strategic partnerships.
10. Loss of reputation: It is currently vital to take steps to ensure effective risk management, choosing partners carefully, and maintaining high standards for product safety and data transparency.
11. Alliances and partnering
12. Reverse brain drain
13. Impact of global healthcare reforms
14. New sources of competition
15. Data privacy and security

Source: The 2009 Ernst & Young Business Risk Report, Life sciences. For more information, visit ey.com.

But a recent study by Deloitte notes that basic differences between the pharma industry in 1984 and the biotech industry in 2009 make it difficult to apply Hatch-Waxman as a model for FOBs legislation.

According to the study, Avoiding No Man's Land: Potential Unintended Consequences of Follow-on Biologics, when the Hatch-Waxman generic drug legislation was enacted in 1984, the pharma industry was stable and mature, and the legislation provided a catalyst for investment and competition.

Pharma innovators earned sufficient returns to continue drug innovation, while generic producers enjoyed increasing volume growth and market penetration.

The biotech industry is markedly different, observes Jim Hollingshead, principal in the health sciences practice of Deloitte Consulting.

"With follow-on biologics, Congress may need to consider a different set of rules to balance cost savings, patient safety, and economic incentives for future innovation," Mr. Hollingshead notes.

The biotechnology industry is comparatively young, and in contrast to pharmaceuticals in 1983, the overall business system that drives it is immature in two key areas: the basic science and the business model.

The business model of biotech is more fragmented and more heavily reliant on risk capital than was its 1983 pharma counterpart.

For more information, visit deloitte.com/us.

Life-Sciences Industry Needs to Demonstrate **VALUE OF INNOVATION**

Government and private insurers are placing unprecedented pressures on life-sciences companies to demonstrate value for the products they develop.

And insurers, governments, and individuals are likely to increase demands to demonstrate value in the years ahead as they confront mounting healthcare costs, a shrinking tax base, aging populations, and a mandate to provide care for a larger pool of citizens.

Meeting this challenge tops the list of the 10 most pressing risks facing the life-sciences industry in 2009, according to Ernst & Young's 2009 business risk report on the sector. Like most of the issues that comprise the list, the need to meet increasingly stringent demands for reimbursement has been exacerbated by the global economic downturn, which is challenging the high-risk/high-reward model that companies have used to fund drug development efforts for several decades.

The economy has prompted large and small companies to sharpen their focus on how they manage scarce capital, boost research and development productivity, and in some cases reinvent a long-held business model to build long-term shareholder value.

"Companies are looking with renewed vigor at how they manage the risks at the very core of their businesses," says Carolyn Buck Luce, global pharmaceutical sector leader at Ernst & Young. "But risk brings opportunity, and the definition of crisis is the crucial stage or turning point. This moment provides the industry with a chance to not only confront these immediate risks, but to take the actions that will strengthen their organizations in more fundamental ways as well."

For more information, visit ey.com.

PHARMACY COST TRENDS At Lowest Level in a Decade

In the midst of the financial crisis and skyrocketing healthcare costs, greater use of generic drugs and lower-cost brand drugs led to a record-low spending trend for 2008, according to data from pharmacy benefit manager Express Scripts.

The overall pharmacy cost trend for Express Scripts clients was 3% for 2008, down from 5.5% in 2007. The findings were calculated by evaluating total prescription costs for traditional drugs and specialty drugs, including patient copayments and payments by plan sponsors, which include employers, health plans, and labor unions.

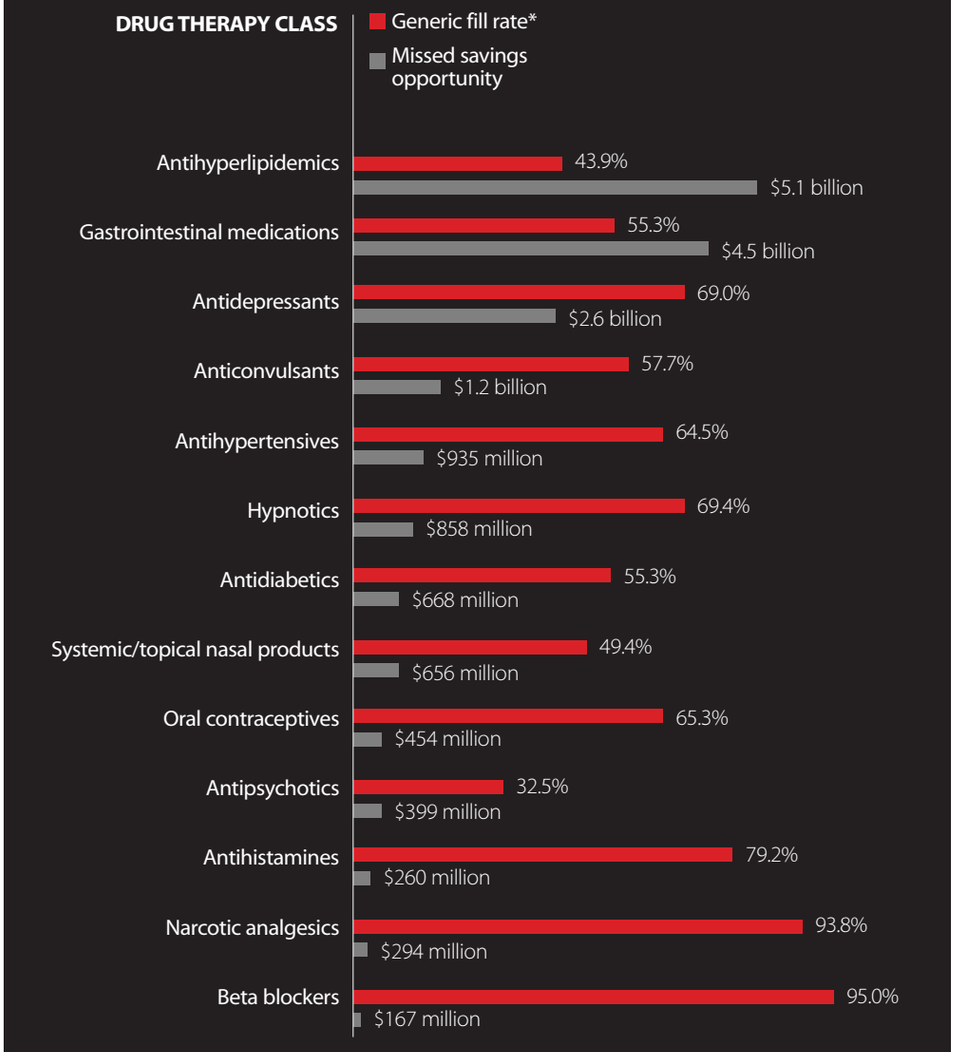
"Using generic drugs that are safe and effective can help lower costs while still driving value for patients and employers," says Steven Miller, M.D., senior VP and chief medical officer at Express Scripts. "Our results indicate that cost control is achievable through careful management of appropriate use of drugs and delivery channels, without shifting costs to consumers."

Despite the continued trend toward reduced drug costs for consumers, significant opportunity to lower spending still exists.

Express Scripts' research shows that failure to make prescription drug choices that take full advantage of clinically appropriate, lower-cost alternatives to more expensive brand drugs cost Americans about $42 billion in 2008. This estimate is based upon potential savings for the total U.S. population in only 13 drug-therapy classes.

For more information, visit express-scripts.com.

GENERIC SAVINGS FROM TOP 13 THERAPY CLASSES FOR 2008



*Actuals through end of 2008

Source: Express Scripts Inc. For more information, visit express-scripts.com.

Mail Service, Higher Generic Use Help Keep **DRUG SPENDING IN CHECK**

Even though brand-name drug-price inflation hit its highest level in five years, increased use of generic drugs limited prescription drug spending growth to 3.3% in 2008, according to a recent report from Medco Health Solutions.

The 2009 Medco Drug Trend Report notes that Medco's drug trend — a measure of spending growth that tracks the year-over-year increases in prescription spending among its client base — faced pressure from brand-name drug price inflation of 8% in 2008. Generic drugs, however, accounted for more than 64% of all prescriptions dispensed last year.

Over the next five years, brand-name drugs with more than $66 billion in annualized sales are scheduled to lose patent protection. The Medco report projects spending growth of 4% to 7% annually through 2011, or an aggregate of 14.7% to 18.0% over the three-year period.

"Under even greater pressure due to the unstable economy, plans are more aggressively pursuing tighter prescription drug management techniques, such as generics and mail order, to both reduce costs and preserve a comprehensive, high-quality benefit for their members," says Medco Chairman and CEO David Snow Jr.

Over the next few years, drug trend will be shaped by several forces including:

• Increase in new and existing specialty and protein-based drugs for common and rare conditions

• High price inflation among branded traditional and biotech brands that lack generic competition

• Unit-cost growth, which will be moderated by the wave of first-time generics for traditional drugs in high-cost categories expected to peak soon after 2011

• Modest increases in treatment rates

• Greater use of therapeutic approaches relying on genomic information and genomic testing in order to personalize therapy

For more information, visit medco.com.

SMALLER, TARGETED SALESFORCES Becoming Standard for Pharma

Frustrated customer groups and leaner economic times have forced a new pharmaceutical sales model to emerge. According to a recent Cutting Edge Information report, the arms race of the previous decade is dead; today, smaller and better-managed salesforces now fill the field.

Faced with the challenge of increasing reach despite salesforce cuts, companies are turning toward building stronger, more personal rep-physician relationships that add value. In the Cutting Edge report, Reinventing Pharmaceutical Salesforces, interviews and surveys with top-performing pharmaceutical and biotech companies revealed that reps now earn more time with their physician targets, have more developed and consultative relationships with their targets, and are more accountable for their territories.

"Some of the more innovative pharma companies started overhauling their salesforces 18 months to 24 months ago," says David Richardson, research team leader with Cutting Edge Information and author of the report. "Now we are starting to see some results, which are largely positive according to our data."

According to the report, one of the negative effects of reduced mirroring is the loss of touches between doctors and companies. Some ways in which companies are replacing these missing touches without raising costs are through e-detailing and the installation of part-time salesforces.

For more information, visit cuttingedgeinfo.com.

Barriers Exist to **ADAPTIVE TRIAL DESIGNS**

Despite the ability of adaptive clinical trials to identify promising drug candidates earlier in the development process, pharma companies have been slow to adopt the model. A recent survey conducted by Perceptive Informatics identified regulatory acceptance concerns, lack of understanding about new techniques, and inability to rapidly access clinical endpoint data as the top barriers to the implementation of adaptive trials.

QUICK LOOKS

Despite a sluggish economy and cuts being made to laboratory budgets, the market for stem cell research products is expected to increase substantially over the next several years, to $688.9 million in 2009 and just under $1 billion by the end of 2011.
Source: BioInformatics, Capitalizing on New Opportunities for Stem Cell Products. For more information, visit gene2drug.com.

The neurodegenerative drug market currently totals $18.5 billion and is expected to increase 62% to $29.7 billion by 2013. The majority of this growth is projected to be in the multiple sclerosis category, which is expected to grow from $12.6 billion to upwards of $20 billion in 2012.
Source: Cutting Edge Information, Neurodegenerative Market Forecast to 2012. For more information, visit cuttingedgeinfo.com.

The approval and launch of highly anticipated oral agents, as well as the increasing use of current and emerging injectable drugs, are expected to drive the overall multiple sclerosis drug market to nearly $10 billion in 2018 in the seven major markets of the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Emerging oral therapies are projected to account for 29% of the market by that time.
Source: Decision Resources, Pharmacor report on Multiple Sclerosis. For more information, visit decisionresources.com.

Despite growing competition from new entrants, microRNA tool providers are witnessing extraordinary growth in their research product portfolios. MicroRNA products generated revenue of more than $20.3 million in 2008, and forecasts expect the U.S. market to reach $98.6 million in 2015.
Source: Frost & Sullivan, U.S. MicroRNA Markets. For more information, visit frost.com.

The Rx-to-OTC market was valued at $6.7 billion in 2008 and is projected to generate annual growth of 8% between 2009 and 2013. Over-the-counter (OTC) medicine use saves American consumers more than $20 billion per year in both direct and indirect costs, and more than one third of American consumers use an OTC medication at least every other day.
Source: Kalorama Information, Rx to OTC Switches 2009. For more information, visit kaloramainformation.com.

In 2008, global revenue from the neurotechnology industry rose 9% to $144.5 billion. Neuropharmaceuticals recorded revenue of $121.6 billion and 9.3% annual growth; neurodevices recorded revenue of $6.1 billion and 18.6% annual growth; and neurodiagnostics recorded revenue of $16.8 billion and 3.7% annual growth.
Source: NeuroInsights, The Neurotechnology Industry 2009 Report: Drugs, Devices and Diagnostics for the Brain and Nervous System. For more information, visit neuroinsights.com.

Since 2000, the number of therapeutic peptides in clinical study has nearly doubled compared with the previous decade's rate, due in part to advances in synthesis, delivery, and formulation technologies. The average annual number of therapeutic peptides entering clinical study worldwide in the period from 2000 to 2007 jumped to 16.9 from 9.7 during the 1990s. There are 48 therapeutic peptides now on the market worldwide, with four having generated global sales of more than $500 million each in 2007.
Source: Tufts Center for the Study of Drug Development, May/June 2009 Tufts CSDD Impact Report. For more information, visit csdd.tufts.edu.

Analysts believe the two M&A deals most likely to occur in the pharma industry over the next several months could be the acquisitions of Bristol-Myers Squibb and Bayer. The companies best-placed to acquire them appear to be Sanofi-Aventis and Novartis, but industry watchers aren't ruling out Johnson & Johnson or GlaxoSmithKline, if the latter's acquisition of Allergan does not come to fruition.
Source: Urch Publishing, Mergers and Acquisitions in the Pharmaceuticals Sector, 2009. For more information, visit urchpublishing.com.

The clinical diagnostic lab testing market is projected to grow more than 90% to reach $98.4 billion in revenue by 2017. An increase in genetic testing, esoteric testing, consumer-driven healthcare, and aging demographics are among the key factors contributing to strong market growth.
Source: Washington G-2 Reports, Lab Industry Strategic Outlook: Market Trends & Analysis 2009. For more information, visit g2reports.com.

Perceptive conducted the survey during the recent webinar, Optimizing Adaptive Trial Designs: Using Simulation Methodologies to Overcome Challenges, which was attended by more than 500 biopharmaceutical industry professionals.

Regulatory acceptance concerns were cited by more than 35% of respondents, followed by lack of understanding about new techniques (more than 33%) and rapid access to clinical endpoint data (more than 28%).

Other barriers identified by respondents included understanding and implementing complex statistical methodologies, as well as difficulties in medication supplies estimation and supply-chain management.

"Formal FDA guidance on adaptive trials implementation is expected later this year and should help to alleviate regulatory acceptance concerns," says Bill Byrom, Ph.D., senior director, product strategy, Perceptive Informatics.

For more information, visit perceptive.com.

Disparities Exist in PHARMACEUTICAL TREATMENT FOR MINORITY PATIENTS

A recent report from the National Minority Quality Forum finds that appropriate medications for a variety of diseases often are underprescribed, overprescribed, or misprescribed for African Americans, Hispanics, and Asian Americans.

The report — Origins and Strategies for Addressing Ethnic and Racial Disparities in Pharmaceutical Therapy: The Health-Care System, the Provider, and the Patient — reveals disparities in the treatment of minority patients with cardiovascular illness, asthma, psychiatric illness, pain, and other conditions, as well as differences in access to medications through insurance programs, in the prescribing of medications, and in adherence to medication regimens.

"Since medications are a cornerstone of treatment for many diseases, addressing unequal or inappropriate medication use should be a focus for practitioners and organizations committed to the goal of eliminating healthcare disparities," says Robert Like, M.D., professor and director of the Center for Healthy Families and Cultural Diversity of the UMDNJ-Robert Wood Johnson Medical School and one of the authors of the report. "We hope this report raises awareness of the extent of medication disparities and will stimulate solutions to address the problem."

The report points out that improving access to and use of medications in diverse groups requires policies that enable affordable, personalized therapy. Ethnic/racial background, like other factors such as age or gender, should be considered in selecting drugs and dosages; in the composition of drug formularies and preferred drug lists; and in determining the scope of drug substitution policies.

For more information, visit nmqf.org.