

## PHARMA TRAX

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

## Biopharma Firms Increasingly Seek **MARKETING ROLE IN LICENSING DEALS**

Large pharmaceutical companies' growing reliance on alliances and in-licensing to gain access to technologies and new molecular entities from biopharmaceutical firms has strengthened the bargaining position for firms offering these assets.

As a result, according to research from Business Insights, licensing deals are becoming more complex and negotiation tactics increasingly aim to expand the role of biopharma firms beyond product discovery and development toward an active participation in the future of their products.

The report, *Evolving Trends in Biopharmaceutical Licensing*, notes that even though traditional pharma still accounts for the bulk of global bio/pharmaceutical sales, biopharmaceutical sales grew at a stronger compound annual growth rate of 15.9% over the 2003-2007 period, compared with pharma's 8.2% CAGR.

The report also observes that recent increases in internal biopharmaceutical consolidation are an indicator of the ability of well-established biopharma companies to effectively compete against traditional big pharma.

Biopharma technology and product licensing peaked in 2005 at 1,057 deals, declined 3.1% to 1,024 deals in 2006, fell still further, 11.1%, to 910 deals in 2007, and plunged 24.2% to 690 deals in 2008.

Analysts believe these declines are indicative of the evolving ability of biopharma to independently develop and bring drugs to market.

The report also examines the growth of the industry, deal-making trend data, drivers and challenges facing biopharma licensing, and deal profiles for leading companies.

The future prospects of the industry are assessed and the potential impact of political/regulatory factors upon licensing and alliances is identified.

For more information, visit [globalbusinessinsights.com](http://globalbusinessinsights.com).

## Pharma Firms Seek to Balance **QUALITY ASSURANCE AND COST REDUCTION**

A majority of pharma companies find that a vertical quality and compliance (Q&C) management structure model effectively increases internal efficiencies compared with a horizontal model, according to a recent study by Best Practices' Global Benchmarking Council. But having a single Q&C organization per function does not help reduce operating costs, an increasingly important challenge in today's economic landscape.

The study, *Quality and Compliance: Optimizing Organizational Structures*, benchmarked organizational models to manage quality and compliance employed by pharmaceutical, biotech, and healthcare manufacturing companies. According to the research, horizontal Q&C models are heavily focused on external rules, while vertical models are centered more on quality measures within each business unit.

Both the horizontal and vertical models are most effective in avoiding regulatory fines and citations, while the vertical model is least effective in supporting career planning.

Although the vertical model is shown to be extremely effective at increasing quality standards within the business unit, it requires proper management to control operational costs, the study notes.

For more information, visit [best-in-class.com](http://best-in-class.com).

## **RECESSION HURTS SOME** but Helps Other Healthcare Sectors

A higher unemployment rate and the resulting increase in the ranks of the uninsured will mean more pain for consumers and for the traditional pharmaceutical industry business model over the next few years.

According to a recent study by Kalorama Information, out-of-pocket spending on healthcare should see an increase, driving consumers to OTC drugs and generics.

The Kalorama report, *Healthcare in a Recession*, estimates that consumers will spend about \$283 billion in nonelective, out-of-pocket healthcare costs between co-pays, premiums, and cash or check payments for prescription drugs and other

### QUALITY AND COMPLIANCE MODELS: OBJECTIVES AND APPROACHES

THE HORIZONTAL MODEL IS ORGANIZED AROUND EXTERNAL RULES THAT AFFECT AN ORGANIZATION.

■ Q org units ■ Other org units

R&D | Mfg | Marketing | Sales | Legal | Finance | Others

■ GRPs

■ GLPs

■ GCPs

■ GMPs

■ GPP

■ All Other Rules

- Separate Q&C groups specialize in each set of rules.
- Q&C groups provide information to multiple functions about compliance to specific types of rules.
- Functions use multiple Q&C groups for information and must integrate findings of each.
- Q&C units coordinate to ensure that there is integration of various rules within functions and across the company.

### THE VERTICAL MODEL ORGANIZES QUALITY IN EACH BUSINESS UNIT OR FUNCTION.

- Compliance & Q org unit / GxPs & Other Rules
- Auditors and specialists ensure that their business unit/function complies with all applicable rules.
- Each function relies on a single Q&C unit to provide Q&C information about all applicable rules.
- Q&C units that support the various functions must coordinate to ensure that all the functions in the company are meeting expectations with regard to quality and compliance.

Source: Best Practices, *Quality and Compliance: Optimizing Organizational Structures*.  
For more information, visit [best-in-class.com](http://best-in-class.com).

**ESTIMATED U.S. GENERIC INDUSTRY GROWTH, 2009-2012**

Industry Value 2009

\$23 billion

Industry Value 2012

\$43 billion

% Change

87.0%

Source: Kalorama Information, Healthcare in a Recession. For more information, visit [kaloramainformation.com](http://kaloramainformation.com).

**ESTIMATED U.S. OTC INDUSTRY GROWTH, 2009-2012**

Industry Value 2009

\$17.7 billion

Industry Value 2012

\$20.3 billion

% Change

14.7%

Source: Kalorama Information, Healthcare in a Recession. For more information, visit [kaloramainformation.com](http://kaloramainformation.com).

services. Since the bulk of out-of-pocket costs are for prescription drugs, this is an area where unemployed and underinsured consumers will be more discriminating.

"Out-of-pocket healthcare spending was already increasing in good times, and now with high unemployment, consumers will be reaching into their pockets even more to fund their healthcare," observes Bruce Carlson, Kalorama publisher. "When it's their money they are spending, it's reasonable to expect they will look to generics and medicines on the shelf where possible."

While the pharmaceutical industry is expected to see reduced sales of prescription drugs, Kalorama estimates U.S. generic sales for 2009 will show a 10% increase over last year. In addition, revenue of manufacturers of OTC drugs is expected to rise 18% in 2009 as consumers seek to avoid the time and cost of physician visits.

For more information, visit [kaloramainformation.com](http://kaloramainformation.com).

## Rise in Online Trade Boards, Pharmacies Heightens **DRUG COUNTERFEITING RISKS**

A two-year study recently released by OpSec Security shows a substantial increase in illicit behavior by trade board sellers that offer bulk pharmaceuticals and active pharmaceutical ingredients (APIs) to buyers and intermediaries, as well as Inter-

net pharmacies that sell drugs directly to consumers.

The study, *Assessing the Risk of Counterfeit Pharmaceuticals in the Online Marketplace*, revealed a 30% rise in the number of listings offering bulk pharmaceuticals and APIs across multiple highly trafficked business-to-business (B2B) trade boards, which are unregulated and often used as a platform for the global sale and distribution of counterfeit pharmaceutical products.

OpSec found that the majority of sellers offering pharmaceutical products and active ingredients are based in Asia. While there has been a slight uptick in sellers based in other countries, sellers from China and India represented 92% to 95% of the results found during the two-year period.

The study also found a 65% increase in the number of Internet pharmacies that do not require a prescription or only require an online consultation before purchasing drugs. In addition to offering significant discounts — sometimes as much as 60% to 80% below retail price — one-third of the Internet pharmacies in OpSec's research exhibited other signs of highly suspicious behavior indicative of illicit drug sales, such as registering outside the United States yet targeting U.S. consumers.

"The continued rise of these trends reveals increasing risks to consumers who buy drugs and companies that source pharmaceutical products online," says Jeffrey Unger, president, brand protection, OpSec Security. "Unfortunately, the easy anonymity, lax regulations, and global reach of the Internet allow counterfeit drugs to enter into the legitimate supply chain."

For more information, visit [opsecsecurity.com](http://opsecsecurity.com).

## Report Examines **COST CONTROLS FOR PUBLIC HEALTH PLAN**

With a new Congress, a new administration, and

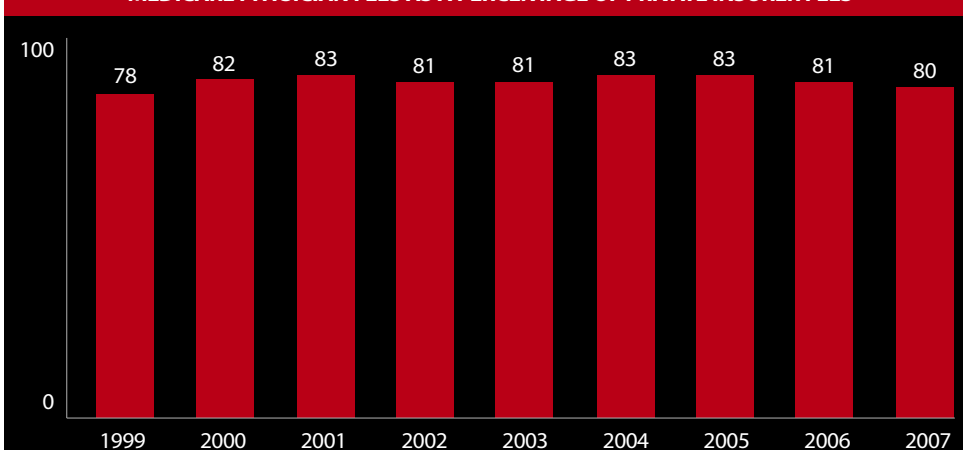
general public and stakeholder support, there is now widespread, bipartisan agreement on the goal of assuring access to affordable, high-quality insurance coverage for millions of uninsured and underinsured Americans. But expanding access to these Americans will significantly increase overall health-care spending, unless meaningful cost-control strategies are also pursued.

A recent issue brief from Avalere Health, *Managing Cost in a Public, Government-Run Plan: Issues and Considerations*, evaluates the three sets of tools currently used by health plans to manage costs: setting appropriate payment rates, influencing the volume of services, and choosing efficient providers. Avalere researchers conclude that the decisions made in each of these areas will directly affect the extent to which a level playing field between the private market and a government-run plan exists, as well as how effectively a new public plan will manage costs.

According to Avalere's brief, a central question facing a public plan is how to set payment levels for providers. One option is for the government-run plan to impose Medicare rates on all providers participating in its plan. The Medicare Payment Advisory Commission (MedPAC) found in January 2009 that Medicare rates to physicians are typically about 80% of commercial payments. Proponents tout this as effective use of Medicare's leverage, while opponents of a public plan note that private plans cannot impose rates on providers and instead rely on annual negotiations.

"Private plans have generally been unable to get rates as low as Medicare, despite many years of negotiations with physicians," says Jon Glaudemans, senior VP of Avalere Health and lead author on the issue brief. "A public plan that can impose Medicare-based rates would, therefore, have a government-sanctioned advantage in the marketplace."

"To be meaningful, a debate over the public plan must get into the specifics about how health-care decisions are made for patients," Mr. Glaudemans says.

**MEDICARE PHYSICIAN FEES AS A PERCENTAGE OF PRIVATE INSURER FEES**

Source: Avalere Health, *Managing Cost in a Public, Government-Run Plan/Issues and Considerations*, citing data from Direct Research LLC and MedPAC analysis. For more information, visit [avalerehealth.net](http://avalerehealth.net).

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mans adds. "Understanding how the government would weigh in on control of healthcare utilization is key to evaluating the effects of these plans and how they would stack up relative to private-sector offerings."

For more information, visit [avalerehealth.net](http://avalerehealth.net).

## EDC ADOPTION Growth Continues Despite Economic Downturn

The use of commercial electronic data capture (EDC) solutions in the life-sciences industry continues to grow as companies seek to more quickly and effectively collect and use clinical data to accelerate time to market for new drugs and devices. Recent research by IDC Health Insights projects that EDC adoption will continue to grow beyond the greater-than-50% use of EDC in new clinical trials estimated in 2008.

The IDC Health report, Market Analysis: The Health Industry Insights e-clinical Buyer's Guide, Part 1, Electronic Data Capture, observes that to pick the right solution from among the myriad of different commercially available EDC options, life-sciences customers need to be able to differentiate EDC vendors based on their specific needs and requirements.

Based on size and revenue, Phase Forward and Medidata are currently the dominant EDC vendors in the industry, according to the report.

"In this increasingly complex global life-sciences ecosystem, companies need to carefully determine how EDC and broader e-clinical solutions can meet their clinical development needs," says Alan Louie, Ph.D., a research director with IDC Health Insights. "Smaller life-sciences companies, in particular, should take notice, since it is becoming increasingly possible to exploit e-clinical solutions directly to perform their own clinical trials."

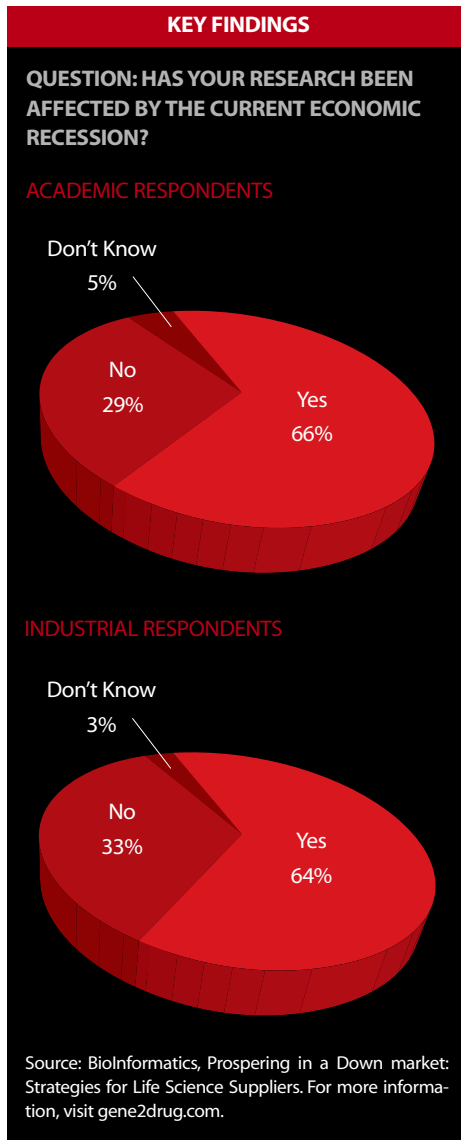
For more information, visit [idc.com](http://idc.com).

## Recession Squeezes LABORATORY STAFFING AND SPENDING

Despite the estimated \$21.5 billion in federal research and development (R&D) funding signed into law earlier in 2009, pharmaceutical, biotechnology, academic, and government labs continue to react to the deepening recession with budget freezes and staff reductions.

An estimated 65% of respondents to a recent Bioinformatics survey say their organizations have implemented hiring freezes, and 63% note their labs are delaying or canceling nonessential purchases.

One key finding of the report, *Prospering in a Down market: Strategies for Life Science Suppliers*, is



that scientists are significantly more price-sensitive than in prior years, and in some product categories they would be willing to incur the hassles of switching to a lower-cost supplier if the price were discounted by only 10% to 12%.

This is in contrast to earlier studies conducted by Bioinformatics, where scientists were unwilling to consider switching vendors in these same categories for any less than a 25% discount. This shift could provide an opportunity for a secondary supplier to move into a primary supplier position, the report observes.

For more information, visit [gene2drug.com](http://gene2drug.com).

## Recessions Historically Have Modest Impact on OTC MARKET

Recent analysis by Kline & Company found that historically during recession years, the overall OTC market grew 1.2%, compared with 3.2% during

nonrecession years, mainly due to an erosion of branded OTC sales by private-label products.

According to the report, *Impact of Recessions on the U.S. OTC Market*, in previous recessionary periods overall OTC sales declined two years in a row; from 1999 to 2000, overall manufacturers' sales were down 0.6%, and then declined again from 2000 to 2001 by 0.5%.

These relatively modest market declines could be a result of sustained private-label sales, the report notes.

Sales of Rx-to-OTC switch brands are either not impacted by recession or are less impacted than regular OTC brands.

For instance, the report observes, the Rx-to-OTC switch of Claritin in 2003 only lost 18% of sales to private-label competitors in the nonrecession period, while private-label equivalents of Zyrtec launched in early 2008 seized one-fourth of brand sales during 2009, a recession year.

"There is clear evidence that private-label OTCs grow at significant rates during a recession," says Laura Mahecha, healthcare industry manager at Kline. "Consumers did trade down to private label, and branded products lost considerable shared private label, but at the same time, several switched products still did really well, as consumers are still willing to pay extra for a product they feel is more innovative and offers more relief."

For more information, visit [klinegroup.com](http://klinegroup.com).

## RECRUITMENT REMAINS MAJOR OBSTACLE to Improving Alzheimer's Treatments

Partnering with local physicians, working with local clinics, and conducting educational seminars and health fairs were found to be the most effective tools in recruiting people for Alzheimer's clinical studies, according to research from one of three studies discussed at a recent Alzheimer's Association meeting.

Patient registries and Internet recruiting were found to be much less successful recruitment strategies, according to staff at the U.S. Alzheimer's Disease Centers (ADCs).

The National Institute on Aging (NIA) funds 30 ADCs at major medical institutions across the nation.

"Second only to inadequate funding, recruiting participants for clinical studies is the single greatest barrier to developing better treatments for Alzheimer's disease," says William Thies, Ph.D., chief medical and scientific officer for the Alzheimer's Association. "These clinical studies give us clear information from sponsor companies that are currently conducting large-scale clinical trials on how we may recruit participants better and faster in the future."

In a second study looking specifically at recruit-

ing African Americans for Alzheimer's genetics studies, researchers in North Carolina and Florida found that having a relative with the disease, use of minority study personnel, and monetary compensation were the most powerful incentives for participation in research.

In addition, partnerships with churches and influential community leaders were found to yield

significantly greater interest and participation in studies.

A third study conducted by a Stockholm-based nurse and colleagues investigated the motives and expectations of people with dementia and their relatives for participating in Alzheimer's clinical research trials.

According to those surveyed, primary motives to

participate were helping science and contributing to research, hope for easing of symptoms or a cure, and getting access to more information about the disease.

In addition, patients and relatives reported that access to medical expertise and regular health checkups were advantages of study participation. For more information, visit [alz.org](http://alz.org).

#### QUICK FACTS

- Between 40% and 50% of uninsured Americans would be covered under Medicaid if current House or Senate reform proposals are enacted, with Medicaid enrollment reaching nearly 85 million Americans over the next several years.

Source: Avalere Health analysis of data from the Kaiser Family Foundation and the Urban Institute's Health Insurance Policy Simulation Model. For more information, visit [avalerehealth.net](http://avalerehealth.net).

- Global sales of liver disease treatments are expected to increase from \$8.4 billion in 2009 to \$9.8 billion in 2014, for a compound annual growth rate (CAGR) of 3% over a five-year period.

Source: BCC Research, Liver Disease Treatments: The Global Market. For more information, visit [bccresearch.com](http://bccresearch.com).

- The global market for proteomics is expected to rise from \$6.7 billion in 2008 to an estimated \$7.9 billion in 2009 and \$19.4 billion in 2014, for a compound annual growth rate (CAGR) of 19.7%.

Source: BCC Research, Proteomics: Technologies and Global Markets. For more information, visit [bccresearch.com](http://bccresearch.com).

- Autoimmune brand revenue is forecast to surge 76% over the next five years to nearly \$70 billion in annual sales, with several products scheduled for 2011 and 2012 expected to easily eclipse \$1 billion in sales by 2014.

Source: Cutting Edge Information, Autoimmune Market Forecast to 2014. For more information, visit [cuttingedgeinfo.com](http://cuttingedgeinfo.com).

- European prices of 170 best-selling drugs averaged 40% less than U.S. prices in 2008. Within Europe, prices varied substantially, from an average of 55% of U.S. prices in Italy to 70% of U.S. prices in Germany.

Source: Decision Resources, Spectrum report, 2009 Chartbook of International Pharmaceutical Prices. For more information, visit [decisionresources.com](http://decisionresources.com).

- The launch and uptake of new anti-amyloid monoclonal antibodies, most notably

Elan/Wyeth's bapineuzumab and Eli Lilly's solanezumab, are expected to be the main drivers of 11% annual growth from 2008 to 2018 in the market for Alzheimer's disease drugs. Together, bapineuzumab and solanezumab are projected to grab just over half of the overall Alzheimer's market by 2018, achieving combined sales of nearly \$6 billion.

Source: Decision Resources, Pharmacor report on Alzheimer's Disease. For more information, visit [decisionresources.com](http://decisionresources.com).

- Generic price erosion, increased product competition, and cost-consciousness are expected to reduce the asthma drug market from \$11.9 billion in 2008 to \$10.1 billion in 2018 in the seven major global markets of the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. The principal factor is the impending loss of brand exclusivity of Merck/Kyorin's Singulair beginning in 2012 in the United States, Europe, and Japan.

Source: Decision Resources, Pharmacor report on Asthma. For more information, visit [decisionresources.com](http://decisionresources.com).

- The market for hepatitis C virus drugs is projected to expand dramatically, from \$2 billion in 2008 to nearly \$7.7 billion in 2013, in the seven major global markets. But the market is then expected to shrink to \$3.4 billion in 2018 as a result of a decline in the prevalence of the disease and the high efficacy of new treatment regimens.

Source: Decision Resources, Pharmacor report on Hepatitis C Virus. For more information, visit [decisionresources.com](http://decisionresources.com).

- The launch of targeted agents, as well as increased use of existing agents in the maintenance setting, is projected to nearly triple growth in the non-small-cell lung cancer (NSCLC) drug market from \$3.5 billion in 2008 to almost \$10 billion in 2018 in the seven major global markets.

Source: Decision Resources, Pharmacor report on Non-Small-Cell Lung Cancer. For more information, visit [decisionresources.com](http://decisionresources.com).

- Sales of Parkinson's disease therapies are anticipated to increase modestly from \$2.5 billion in 2008 to \$2.8 billion in 2018 in the seven major global markets, as the launch of several new therapies is offset by generic erosion of key currently available agents.

Source: Decision Resources, Pharmacor report on Parkinson's Disease. For more information, visit [decisionresources.com](http://decisionresources.com).

- The worldwide market for oral drugs using drug delivery technologies has experienced tremendous growth over the last few years, with revenue at the manufacturer's level of \$43 billion for both major technologies in oral delivery and the products that use these delivery technologies. The market is expected to reach \$71 billion by 2013, with a compound annual growth rate (CAGR) of almost 11% for the five-year period beginning in 2009.

Source: Kalorama Information, Drug Delivery Markets: Oral Delivery. For more information, visit [kaloramainformation.com](http://kaloramainformation.com).

- The market for electronic medical records (EMR) data transfer equipment and applications has been valued at an estimated \$575 million in 2008 and is projected to reach \$1.6 billion in 2013.

Source: Kalorama Information, High-Tech Patient Monitoring Systems Markets (Remote and Wireless Systems, Data Processing, EMR Data Transfer). For more information, visit [kaloramainformation.com](http://kaloramainformation.com).

- Global sales of vaccines jumped 21.5% to \$19.2 billion in 2008, and the market is forecast to more than double by 2013 due to a strong pipeline of new products and rising usage of current products around the world.

Source: Kalorama Information, Vaccines 2009: World Market Analysis, Key Players, and Critical Trends in a Fast-Changing Industry. For more information, visit [kaloramainformation.com](http://kaloramainformation.com).