

Companies Advised to **COMMUNICATE WITH PAYERS EARLIER** in Drug Development

Payer groups are now demanding more data, outcomes research, and standardized submissions from pharmaceutical companies before agreeing to cover a new drug. Yet research from Cutting Edge Information shows companies rarely contact payers before their drug reaches Phase III development. By not contacting payers earlier in the process, pharma companies are missing an opportunity to gain a better understanding of payers' needs and forge stronger relationships with these key market players.

According to Cutting Edge's study, *Securing Market Access: Reimbursement, Payer Relationships and Healthcare Reform*, the number of conversations between account managers and payers increases throughout a drug's development cycle and peaks at 15.1 during the regulatory approval and launch stage, more than at all other phases of development combined. By contrast, the study finds that drug companies contact payers an average of 2.4 times in all of Phase II.

The number of contacts with payers in the final stages before launch often results from mistakes made on the formulary submission documents. Payers ask that corrections be made and request additional information that was not submitted with the original drug dossier, adding days and even weeks to the submission process and potentially delaying a drug's launch. Common errors can multiply, overwhelming even the most experienced account manager.

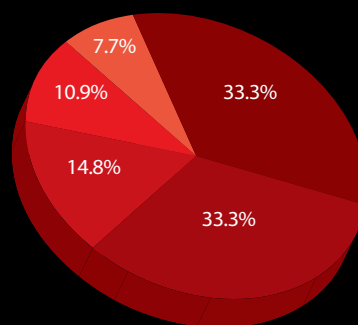
The study's researchers observe that companies can avoid most mistakes by communicating clearly and regularly with payers throughout the early stages of drug development. Extra phone calls, e-

mails, or face-to-face visits with payers help account managers better understand payer requirements and preferences and enable the manager to communicate the information to the market access department well before preparing the final submission.

"Improving how drugmakers communicate early in the development process produces stronger, more competitive products by increasing cooperation with payers during registration and launch," says Cutting Edge President Jason Richardson. "Providing more valuable information to payers during early-stage drug development and reducing later 'firefighting' is critical for market access teams." For more information, visit cuttingedgeinfo.com.

AVERAGE ALLOCATION OF A MANAGED MARKETS DEPARTMENT'S PERSONNEL

- Account Manager
- Marketing
- Sales Manager
- Other
- Administrative



Source: Cutting Edge Information, *Securing Market Access: Reimbursement, Payer Relationships and Healthcare Reform*. For more information, visit cuttingedgeinfo.com.

Pharma Companies Add **EMPLOYER MARKET** to the Mix

Companies are seeking ways to serve the underappreciated employer market in a complementary approach to the traditional pharma commercial model. Efforts focus on building long-term business relationships and working as a consultative partner that can help employers improve not only health outcomes for employees but also business outcomes in general.

The recent Best Practices report, *Serving the Healthcare Needs of Employers: Employer Market Strategies and Tactics*, notes that at companies with more than 5,000 employees, the primary target of pharma industry outreach, 73% of pharmaceutical account managers call on medical directors and

human resource managers to begin raising awareness about disease states and treatment paradigms. Study participants emphasize, however, that working in the employer space should not be seen as a traditional sales effort, but rather as an opportunity to articulate a value proposition that does justice to the needs of this audience.

For more information, visit best-in-class.com.

EMPLOYER PROGRAMS FOCUS ON EDUCATION, AWARENESS

According to respondents, programs for educating and raising awareness among employees are most common. Other programs cited by respondents include value propositions, discount programs, online training, outcomes pilot participation, value-based benefit design, and behavioral change programs.

Q: What types of programs does your company offer to employers? (multiple responses)



* Other programs include: value propositions, discount programs, online training, outcomes pilot participation, value-based benefit design, behavioral change.

Source: Best Practices, *Serving the Healthcare Needs of Employers: Employer Market Strategies and Tactics*. For more information, visit best-in-class.com.

Healthcare Companies Continue to Make Strides in **SUPPLY CHAIN**

With U.S. healthcare spending estimated at an unsustainable 16% of GDP, the second-highest percentage among United Nations member countries, healthcare in the United States is at a historic turning point. According to AMR Research, supply-chain leadership and best practices can play a major role in helping to transform the industry and in guiding U.S. healthcare toward its goal of delivering high-quality, cost-effective patient care.

The AMR Research Healthcare Top 25 for 2009 identifies those healthcare companies that have

THE AMR RESEARCH HEALTHCARE TOP 25 FOR 2009

1. Johnson & Johnson
2. Sisters of Mercy
3. Cardinal Health
4. Owens & Minor
5. McKesson
6. CVS Caremark
7. Abbott
8. Novartis
9. BD (Becton, Dickinson)
10. Wyeth
11. GlaxoSmithKline
12. AstraZeneca
13. AmerisourceBergen
14. Walgreens
15. Covidien
16. Cleveland Clinic
17. Merck
18. Genentech
19. Alcon Laboratories
20. Medtronic
21. Boston Scientific
22. BJC HealthCare
23. Roche
24. Amgen
25. Mayo Clinic

Source: AMR Research.
For more information, visit amrresearch.com.

best embraced the concept of demand-driven supply chains. The companies were ranked based on financial metrics (return on assets and inventory turns) and peer and analyst opinion of each company's operational efficiency.

"The healthcare industry's attitude toward supply chain innovation is changing," observes Hussain Mooraj, VP of AMR Research's healthcare practice. "Supply chain is gaining recognition as a key enabler of the core mission in healthcare organizations."

Three pharmaceutical companies made AMR Research's top 10 in 2009. According to AMR, No. 1-ranked Johnson & Johnson has instituted a series of targeted, enterprise-wide initiatives that focus both on the customer and operational efficiencies of the supply chain. J&J strengthens these internal initiatives by actively participating in industry forums and engaging key hospital customers in supply chain pilots aimed at identifying and unlocking joint value.

Abbott, ranked seventh, employs leading programs to capture voice-of-the-customer insights into supply-chain processes. This focus on the customer is evident from its branded pharmaceuticals to its consumer healthcare businesses. No. 8-ranked Novartis maintains an intense focus on the develop-

ment of lean operations and demand-driven supply chain capabilities, employs a robust global sales and operations planning (S&OP) process, and leverages enterprise technology to streamline communications with upstream contract manufacturers.

For more information, visit amrresearch.com.

Diversification May Not Cushion Big Pharma's Fall Over 'PATENT CLIFF'

Large pharmaceutical companies are working hard to implement strategies such as diversification to lessen the impact of the upcoming loss of patent protection on some of the industry's biggest sellers on their collective bottom lines. But analysts at Datamonitor caution that diversifying away from the core business of developing prescription drugs is not the cure to the pending ails of big pharma's impending 'patent cliff'.

According to the report, Mapping the Healthcare Landscape: Bringing Pharmaceuticals into Focus, Datamonitor research shows that between 2001 and 2008, the collective revenue of big pharma companies grew at an annual rate of 8.6%. If maintained, this rate of growth would result in total revenue of \$628 billion in 2014. But Datamonitor forecasts revenue growth across the big pharma companies will flatline at 0.2% over the next several years, for estimated sales of \$387 billion in 2014.

As the industry seeks to maximize operational efficiencies in the face of the current economic climate and the much-anticipated patent cliff, some large companies are considering diversifying away from the branded pharmaceuticals sector. The Datamonitor study observed that companies for which pharmaceuticals accounted for more than 90% of 2008 revenue (such as AstraZeneca, Eli Lilly, Pfizer, and Merck) had above-average operating margins, while operating margins were below average for companies with a more intermediate pharma focus (such as GlaxoSmithKline, Roche, Sanofi-Aventis, and Bristol-Myers Squibb) and those that were diversified (such as Bayer, Johnson & Johnson, Abbott, and Novartis).

"In broad terms, Datamonitor's analysis indicates that moving toward and remaining in the branded pharmaceutical sector offers the greatest rewards," notes Dr. Pam Narang, Datamonitor pharmaceutical strategy analyst. "But it should be noted that the path a given company takes will depend very much on its starting position."

For more information, visit datamonitor.com.

Pharma Strives to Tighten SPEND REPORTING Procedures

State reporting requirements on life-sciences companies' spending activities are becoming more

and more complex, and as laws continue to be enacted on both the state and federal levels, the pharmaceutical, medical device, and biotech industries are being forced to make greater improvements in the completeness and accuracy of reporting procedures.

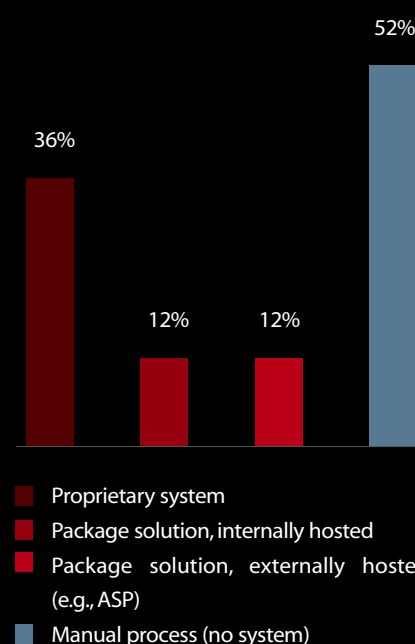
According to Huron Consulting Group's 2009 survey on aggregate spend practices, identifying all the healthcare practitioner (HCP) and healthcare organization (HCO) touch points across an organization is a critical step in defining a data capture strategy. This includes capturing direct and indirect data from the various systems and vendors that support business functions across the organization. In most organizations, payments are tracked by different groups, and data often reside in disparate systems.

Respondents to the Huron study indicate that manufacturers are using multiple channels, rather than relying on one channel, to track fee-for-service payments and meal and travel reimbursements to HCPs and HCOs. In anticipation of the Sunshine Act, many manufacturers have taken steps to begin tracking and collecting HCP and HCO payments across a broader scope: 45% of respondents currently track payments in all states, while 52% indicated that they currently track payments only for affected states.

For more information, visit huronconsultinggroup.com.

SYSTEMS FOR TRACKING SPEND DATA

Q: How does your organization capture, integrate, track, and report state spend data?



Source: Huron Consulting Group, 2009 Aggregate Spend Survey. For more information, visit huronconsultinggroup.com.

QUICK FACTS

- The majority of asthma patients responding to the Asthma Insight and Management (AIM) survey think their condition is well-managed, with more than 70% of patients surveyed believing that their asthma is either completely or well-controlled. But 47% of these patients were actually classified as having very poorly controlled asthma according to the survey's classification of control, which is based on accepted guidelines, and another 24% were defined as not well-controlled.

Source: Asthma Insight and Management survey, conducted by Abt SRBI Inc. in the summer of 2009. For more information, visit takingaimatasthma.com.

- Sales of agents to treat acute ischemic stroke are expected to remain relatively flat over the next decade, increasing to \$450 million in 2018 from \$360 million in 2008 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Anticipated near-term advances in the treatment of this indication include broadening the use of recombinant tissue plasminogen activator (rt-PA) and innovative therapies such as stroke devices.

Source: Decision Resources, Pharmacor report on Acute Ischemic Stroke. For more information, visit decisionresources.com.

- Biosimilars of TNF-alpha inhibitors stand to erode \$9.6 billion in brand sales in the United States, France, Germany, Italy, Spain, and the United Kingdom by 2018, while at the same time saving healthcare systems \$4 billion. While gastroenterologists and rheumatologists have a conservative attitude toward use of these biosimilars compared with physicians in other specialties (e.g., oncologists), survey results suggest that pressure from payers will override their discomfort and push them to prescribe these agents.

Source: Decision Resources, Biosimilars: TNF-Alpha Inhibitors and Interferon-Alphas in Immune and Infectious Disease. For more information, visit decisionresources.com.

- Widespread generic erosion of branded atypical antipsychotics such as AstraZeneca's Seroquel and Eli Lilly's Zyprexa is expected to cause the bipolar disorder drug market to decline to about \$5 billion in 2018, from \$6.3 billion in 2008, in the United

States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

Source: Decision Resources, Pharmacor report on Bipolar Disorder. For more information, visit decisionresources.com.

- Driven by the continued dominance of immediate-release morphine and novel fast-acting opioid reformulations, the cancer pain drug market is forecast to reach \$3.7 billion in 2018, up from \$2.3 billion in 2008, in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. The market segment for breakthrough pain, acute flares of pain on a background of controlled chronic pain, is expected to experience the most robust annual growth, increasing by more than 15% annually between 2008 and 2018.

Source: Decision Resources, Pharmacor report on Cancer Pain. For more information, visit decisionresources.com.

- The gastric cancer drug market, driven by the launch of several targeted agents over the next few years, is expected to more than double to an estimated \$1.5 billion in 2018, from about \$700 million in 2008, in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

Source: Decision Resources, Pharmacor report on Gastric Cancer. For more information, visit decisionresources.com.

- The increasing prevalence of methicillin-resistant *Staphylococcus aureus* (MRSA) and the uptake of several premium-priced emerging therapies will drive the MRSA market to grow to more than \$1 billion in 2018, up from \$740 million in 2008, in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Three emerging therapies — Theravance/Astellas' telavancin, Johnson & Johnson/Basilea's ceftobiprole, and Forest/AstraZeneca/Takeda's ceftaroline — are expected to capture more than one-third of the overall MRSA market in 2018.

Source: Decision Resources, Pharmacor report on Methicillin-Resistant *Staphylococcus Aureus*. For more information, visit decisionresources.com.

- The launches of several novel therapies are expected to boost the neuropathic pain drug market to \$9.7 billion by 2018, up from \$6 billion in 2008, in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. NeurogesX/Astellas' Qutenza will likely be the most successful of these launches, because of its long-term efficacy for localized peripheral

neuropathic pain and minimal risk of systemic side effects. Sales of Qutenza are forecast to be almost \$700 million in 2018.

Source: Decision Resources, Pharmacor report on Neuropathic Pain. For more information, visit decisionresources.com.

- Continued uptake of marketed and emerging TNF-alpha inhibitors and interleukin inhibitors will likely drive the psoriasis drug market to about \$5.2 billion in 2018, up from \$3 billion in 2008, in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Abbott/Eisai's Humira is expected to emerge as the psoriasis market leader in 2018, with blockbuster sales of \$1.3 billion.

Source: Decision Resources, Pharmacor report on Psoriasis. For more information, visit decisionresources.com.

- Pfizer's \$68 billion acquisition of Wyeth in 2009 will help bolster the company against the impending patent expirations and subsequent loss of revenue from blockbuster drugs such as Lipitor. Before the acquisition, analysts had been predicting that Pfizer would lose an estimated 38.5% — or \$21 billion — in sales by 2013 to patent expirations. Post-merger, analysts are now forecasting 34.7% in lost sales for Pfizer over the next five years.

Source: Frost & Sullivan Market Insight, The M&A Trend Continues: An Analysis of the Key Mergers and Acquisitions of 2009. For more information, visit frost.com.

- The pharmaceutical and biotech industries appear to be weathering the current economic storm, recording \$5.6 billion in construction starts during the third quarter of 2009. The total investment value is spread over 185 separate projects, resulting in an average project investment of \$30 million.

Source: Industrial Info Resources, Pharmaceutical Tracker Online Database. For more information, visit industrialinfo.com.

- The global stem cell market is estimated to reach \$88.3 billion by 2014, growing at a compound annual growth rate (CAGR) of 14.8% over the next five years. The U.S. currently holds a 60% share of the global stem cell market, and forms an especially lucrative market for areas such as bone marrow transplantation through stem cells.

Source: MarketsandMarkets, Global Stem Cell and Advanced Technologies Market (2009 - 2014). For more information, visit marketsandmarkets.com.

China Poised to Become WORLD'S TOP RESEARCH PRODUCER

Over the past several years, there has been explosive growth in research output from China, far outpacing research activity in the rest of the world. At this pace, industry observers predict that China will overtake the United States in research output within the next decade.

A recent Thomson Reuters study, Global Research Report: China, found that China's output increased from just over 20,000 research papers in 1998 to nearly 112,000 in 2008, surpassing Japan, the United Kingdom, and Germany and now standing second only to the United States. China's research is concentrated in the physical sciences and technology, with materials science, chemistry, and physics predominating. The study predicts rapid growth in agricultural sciences and life-sciences fields such as immunology, microbiology, and molecular biology and genetics.

"If China's research growth remains this rapid and substantial, European and North American institutions will want to be part of it," observes Jonathan Adams, director of research evaluation at Thomson Reuters. "China no longer depends on links to traditional G8 partners to help its knowledge development. When Europe and the United States visit China, they can only do so as equal partners."

For more information, visit thomsonreuters.com.

More R&D Funding Leading to More Drug Approvals for **NEGLECTED DISEASES**

New products to treat neglected diseases such as malaria and typhoid are receiving marketing approval from regulatory agencies at a steadily increasing rate as R&D funding for those diseases increases.

According to a recent study by the Tufts Center for the Study of Drug Development, the annual rate of new product approvals worldwide for neglected diseases increased to an average of 2.6 from 2000 to 2009, compared with 1.8 in the 1975-99 period.

"While increased approvals are necessary to improve access, policymakers need to ensure that safe, effective, and easy-to-administer products are adopted by healthcare systems and providers on a consistent basis, that they are affordable, and that they reach the people who need them," says Joshua Cohen, senior research fellow at Tufts CSDD Director of Economic Analysis and author of the study.

The Tufts CSDD analysis examined the results of a widely circulated 2002 study, which reported that only 16 of 1,393 new chemical entities marketed

between 1975 and 1999 targeted tropical diseases and tuberculosis, though Tufts CSDD found that 33 was a more accurate count for the period. The earlier study prompted governments, nonprofit foundations, and private-public partnerships to increase funding for neglected diseases, from less than \$100 million annually a decade ago to more than \$2.5 billion annually by 2009.

According to the Tufts CSDD analysis, drugs to treat HIV/AIDS and malaria accounted for 81% of approvals during the 2000 to 2009 period. Also, vaccines have displaced drugs as the main products being developed for neglected diseases, accounting for 76% of all products in development to treat these conditions.

For more information, visit csdd.tufts.edu.

VACCINE SALES Spur Ancillary Market Growth

Highly publicized vaccine products not only boost the bottom lines of pharmaceutical companies, but also benefit insurance companies, doctors, and retailers, all of whom benefit from sales of ancillary products related to vaccine administration.

According to Kalorama Information's analysis of

the recent flu vaccine season, the roughly \$5 billion market from ancillary products sold as a result of vaccines included office visit copays, retail clinic fees, and indirect shopping revenue. This is in addition to the intangible public relations benefits that many healthcare organizations realized from flu shots, particularly those specifically targeting the H1N1 virus.

"Among the reasons vaccines are a popular play now in pharma is that makers can count on many partners in the distribution process," says Kalorama Publisher Bruce Carlson. "The flu vaccine had demonstrated that retailers, providers, and insurance companies all have incentives to piggyback off the focus on vaccine products, and we expect that to be the same with new products."

The H1N1 vaccine has spurred media interest in vaccines, as well as predictions of vaccines for a host of new diseases. Following the first multibillion dollar cancer vaccine blockbuster Gardasil, drugmakers are promising more cancer vaccines on the horizon against the likes of colorectal, lung, breast, and prostate cancers. Kalorama's report, *Emerging Cancer Vaccines: Market Forecasts, New Developments and Pipeline Analysis, 3rd Edition*, forecasts cancer vaccine sales will more than double to \$4.2 billion by 2012 from \$1.8 billion in 2008.

For more information, visit kaloramainformation.com.

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