PHARMA TRAX

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

Process Inefficiencies Cause $11 Billion in Annual PHARMA REVENUE LEAKAGE

According to recent research by IDC Health Insights, pharmaceutical companies lose an estimated 4.4% in revenue annually due to process inefficiencies surrounding claims management and drug reconciliation within the pharmaceutical sales channel.

That means that in 2009, based on estimated U.S. pharma sales of $252 billion, revenue leakage cost manufacturers $11 billion in lost sales.

For its study Business Strategy: Revenue Leakage — Pharma's $11 Billion Problem, IDC Health Insights surveyed 151 industry leaders and conducted in-depth interviews with 23 pharmaceutical companies to identify channel leakage points and quantify lost revenue.

"Our study results illustrate a troubling reality for manufacturers, but there's good news: short-term leakage can be reduced and, over the longer term, largely eliminated," says Eric Newmark, research manager for IDC Health Insights' commercial life-sciences practice and author of the study.

Industry serialization and pedigree initiatives offer longer-term promise, but there are several process improvements that companies can make now to better align information flow and financial transactions with physical product flow, thereby reducing revenue leakage.

According to the study, over the past 18 months revenue leakage has attracted attention at the C-level, which should help chargeback and rebate teams secure the funding they need to improve system capabilities through badly needed IT upgrades.

The study found many pharma companies currently use systems that are more than six years old for claims management and drug reconciliation, and these systems don't allow for intelligent and efficient processing of the rich proliferation of data now available.

For more information, visit idc-hi.com.

KEY FINDINGS OF REVENUE LEAKAGE STUDY

- Manufacturers, on average, lose 4.4% of annual revenue through reconciliation process inefficiencies. Many company-specific factors influence this percentage, but most companies fall into the range of 3.9% to 4.7%.
- Major leakage points include chargeback discrepancies, duplicate chargebacks, omitted reverse chargebacks, rebate errors, return discrepancies, and concealed shortages.
- 63% percent of manufacturers believe chargeback-related revenue leakage is a serious problem, up almost 25% from a similar survey in 2006.
- On average, manufacturers overpay managed care rebates by 5.5% (with some cases exceeding 10%) and overpay Medicaid rebates by 4.5% (with some cases exceeding 8%).

Source: IDC Health Insights, Business Strategy: Revenue Leakage — Pharma's $11 Billion Problem. For more information, visit idc-hi.com.

Drug Companies Still Under Pressure to Increase PACE OF DEVELOPMENT

Although pharmaceutical developers are improving R&D efficiency, in part by terminating more unpromising drugs earlier in development, their continued success will depend on how well they partner with other firms at specific points on the development spectrum, according to recent research by the Tufts Center for the Study of Drug Development.

"Developers have made important progress in reducing R&D times, but because only three in 10 new drugs, on average, generate sufficient revenue to sustain R&D, pharmaceutical and biotech firms are under great and growing pressure to generate revenue to bring more products to market," observes Tufts CSDD Director Kenneth I. Kaitin. "The simple fact is that product launches are not keeping pace with patent expirations."

Tufts CSDD projects worldwide sales for all drugs coming off patent from 2009 through 2012 will exceed $88 billion.

On average, it currently costs more than $1 billion and takes more than seven years from the start of clinical trials to conduct the necessary studies and win approval to market a new drug in the United States.

One of the near-term trends cited in Tufts CSDD's Outlook 2010 report on pharmaceutical and biopharmaceutical trends is that more firms are focusing on improving clinical protocol design to help reduce trial costs and speed development cycles to mitigate a trend toward increased protocol complexity.

KEY NEAR-TERM TRENDS IN PHARMA DEVELOPMENT

- After the U.S. Congress concludes the current healthcare reform debate, a more activist Food and Drug Administration will focus on a regulatory pathway for follow-on biologics approvals, over-the-counter product and drug safety, foreign facility inspections, preventable deaths from chronic diseases, and vaccine manufacturing capacity.
- Clinical development time for novel protein products, which now averages seven years, is unlikely to decrease due to disease complexity, growth of study protocols that lengthen studies, and difficulty recruiting and retaining volunteers.
- Off-label prescribing of biopharmaceuticals in the United States will be subject to increased economic scrutiny, such as comparative effectiveness assessments, drug utilization reviews, and prior authorization.
- A tougher global operating environment that is forcing marginal research sites to exit clinical development will ultimately create a less fragmented global development landscape; higher-performing research investigators will be available to partner with sponsors.

Source: Tufts Center for the Study of Drug Development, Outlook 2010. For more information, viist csdd.tufts.edu.

Mr. Kaitin notes that while new technologies and improved protocol designs are helping to improve R&D efficiency, "future success for many

sponsors will depend on their ability to collaborate with other drug companies and how well they engage and partner with outside service providers."
For more information, visit csdd.tufts.edu.

MARKET FOR MULTIPLEX ASSAYS Remains Vital

Pharmaceutical companies are increasingly committing to associating their drugs with diagnostic assays. While the majority of these are single-analyte biomarkers, a number of multiplex biomarkers not directly associated with particular drugs are in use as approved or homebrew diagnostics, and these contribute in various ways to the broad field of translational medicine.

The Insight Pharma Reports study, Multiplex Assays: Evolving Technologies, Applications and Future Directions, notes that all major pharmaceutical companies have significant biomarker discovery and implementation programs, and a few are focused on personalizing medicine through use of companion diagnostic assays. Since pharma firms are generally not experienced in the commercialization of such assays, they have tended to establish collaborations of various types with biomarker discovery, technology platform, and integrated in-vitro diagnostic companies.

Multiplex or multi-analyte transcriptomic assays for breast cancer prognostication have been on the market for several years. Following their introduction, at least two companies have begun offering transcriptomic assays for determining the tissue origin of malignant tumors, and a number of companies appear to be pursuing new multiplex or multi-analyte assays for various conditions.
For more information, visit insightpharmareports.com.

Small Business Stands to Benefit from HEALTHCARE REFORM

Only 38% of small businesses with fewer than 200 employees were able to offer healthcare coverage for their employees in 2008, down from 67% in 1995, whereas companies with more than 200 employees covered their employees 99% of the time, according to a recent National Small Business Association survey.

According to the Frost & Sullivan Market Insight report, Implications of Health Care Reform for Small Business in the United States, the proposed reforms would address many of the problems that small businesses face with respect to healthcare. Creating insurance exchanges would force insurance plans to compete for business and allow small businesses to pool risk, streamline administrative cost, eliminate the need for brokers, and gain access to a public option plan. Many small businesses with low-wage workers would also be eligible for significant tax credits that would subsidize their coverage. These savings would enable businesses to devote more of their money to their businesses and generate more profits.

Workers would benefit as well. In all, 70% of uninsured Americans come from families with one or two full-time workers, most of whom are employed by small businesses that offer either unaffordable benefits or no coverage at all. Addressing the issue of lack of health coverage for small businesses could go a long way toward achieving healthcare for many more people.

Moreover, health insurers would not be allowed to prescreen employees for preexisting conditions, considerably helping those who really need healthcare coverage.
For more information, visit frost.com.

Pharma Researchers Predict HIGHER RESEARCH BUDGETS FOR 2010

The life-sciences industry has begun to recover from the tumultuous economic climate of the past year. The $8.2 billion appropriated to the National Institutes of Health Scientific Research program by the American Recovery and Reinvestment Act (ARRA) is being earmarked for lab renovations, challenge grants, the shared instrumentation program and research that spans multiple public and non-profit institutions, all of which will have an immediate and long-term impact on the life-sciences tools industry.

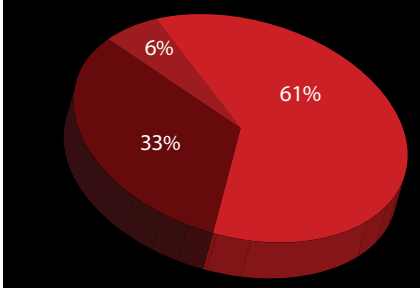
According to the BioInformatics report, The Market Outlook for Research Products in fiscal year 2010, researchers predict their 2010 budgets will be 4.5% higher on average than their budgets for 2009. On the whole, academic respondents foresee slightly larger budget increases (5.5%), while industrial respondents expect somewhat smaller budget increases, the report says.

"While the overall projections for growth in researchers' fiscal year 2010 research budgets are generally positive, differences by geographic region and market segment with respect to funding sources and budget realities will impact not only the spending practices of various labs, but also their receptivity to life-sciences suppliers and their marketing and advertising campaigns," says Tamara Zemlo, Ph.D., MPH, VP of advisory services at BioInformatics.

"Suppliers that are sensitive to a researcher's perceptions of the economy and how it is affecting their science are more likely to maintain good customer relations if they offer promotions that specifically address their customers' concerns."
For more information, visit gene2drug.com.

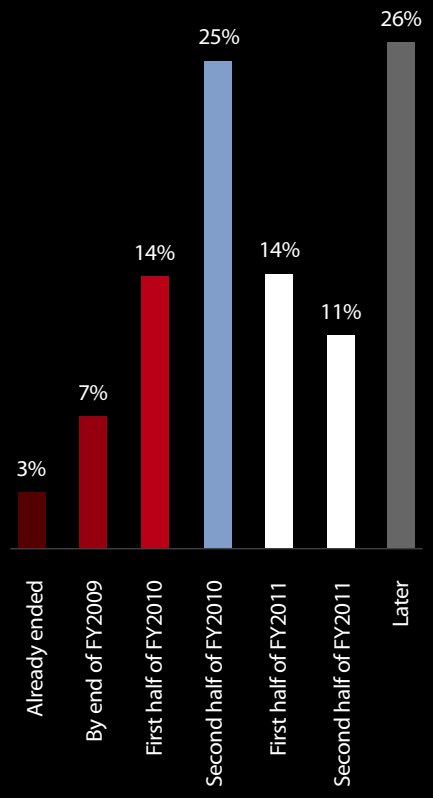
RESEARCH BUDGETS OUTLOOK

Q: Did you or someone in your lab apply for recovery act grant(s) supported by the ARRA?



Note: Only respondents who indicated they perform most of their research/work in the United States and indicated they would best describe their organization as academic, hospital or university medical center, or private research institute answered this question.
Source: BioInformatics, The Market Outlook for Research Products in FY2010. For more information, visit gene2drug.com.

Q: When do you believe the economic recession will end for the life sciences in the United States?



Source: BioInformatics, The Market Outlook for Research Products in FY2010. For more information, visit gene2drug.com.

QUICK FACTS

- The value of current antibiotics and new products in the global market, estimated at $41.5 billion in 2009, is expected to increase to $65.5 billion in 2014, for a five-year compound annual growth rate (CAGR) of 9.6%. The five-year CAGR for the antibiotic drug segment is forecast at 5.9%, while the bacterial vaccines segment's CAGR is expected to soar 31.6% over the next five years.

Source: BCC Research, Antibiotic Resistance and Antibiotic Technologies: Global Markets. For more information, visit bccresearch.com.

- The value of the global market for drugs to treat asthma and chronic obstructive pulmonary disease (COPD) is estimated at almost $27 billion in 2009 and is expected to increase to $31.4 billion in 2014, for a five-year CAGR of 3.3%. The asthma drugs segment is expected to increase at a CAGR of 1.2%, while the COPD drugs segment is forecast to achieve a five-year CAGR of 6.1%.

Source: BCC Research, Global Markets for Asthma and COPD Drugs. For more information, visit bccresearch.com.

- The global market for renal disease treatments reached an estimated $28 billion in 2009 and is expected to increase to $33.5 billion in 2014, for a five-year CAGR of 3.7%. Within that market, the chronic kidney disease segment is projected to grow at a CAGR of 3.6% through 2014, while the five-year CAGR for the acute renal failure segment is forecast at 8.7%.

Source: BCC Research, Renal Disease Treatments: Products and Therapies. For more information, visit bccresearch.com.

- Symptom improvement is the most important drug attribute influencing surveyed U.S. and European urologists' prescribing decisions in benign prostatic hyperplasia/male lower urinary tract symptoms. GlaxoSmithKline's Duodart, a fixed-dose combination of dutasteride and tamsulosin, is expected to earn proprietary clinical gold standard status in 2013 and through 2018 for the treatment of benign prostatic hyperplasia/male lower urinary tract symptoms because of its competitive advantage in overall efficacy over the current gold standard dutasteride, sold by GlaxoSmithKline as Avodart and Taiho Pharmaceutical as Avolve.

Source: Decision Resources, DecisionBase 2010 report — Benign Prostatic Hyperplasia/Male Lower Urinary Tract Symptoms: More Convenient Therapies Targeting Improved Patient Compliance Are on the Horizon. For more information, visit decisionresources.com.

- According to surveyed U.S. cardiologists, a hypertension drug that requires less-frequent dosing than Novartis' Diovan/Tareg (valsartan) would likely earn 30% patient share, significantly higher than Diovan/Tareg's 6.1% share and higher than the patient share achieved by any current hypertension drug. These estimates indicate cardiologists' concern about patient compliance to therapy and their desire for an effective drug that requires less-frequent dosing than Diovan/Tareg.

Source: Decision Resources, DecisionBase 2010 report — Hypertension: Among Fixed-Dose Combination Agents, AIIRA/CCBs Stand Out for Their Superior Efficacy and Safety. For more information, visit decisionresources.com.

- Surveyed U.S. gastroenterologists project that a biological therapy with a mechanism of action other than tumor necrosis factor alpha (TNF-alpha) inhibition for the treatment of moderate-to-severe ulcerative colitis would earn a 25% patient share. These findings highlight the significant opportunity for a biological therapy with a novel mechanism of action to serve as an alternative to Centocor Ortho Biotech/Merck/Mitsubishi Tanabe Pharma's Remicade for the treatment of moderate-to-severe ulcerative colitis.

Source: Decision Resources, DecisionBase 2010 report — Ulcerative Colitis: Gastroenterologists Identify Emerging Drugs That Will Challenge the Benchmark Therapy Infliximab for Moderate to Severe UC. For more information, visit decisionresources.com.

- Generic erosion of premium-priced branded agents to treat acute coronary syndrome is projected to offset sales of new agents, causing the market for acute coronary syndrome drugs in the hospital setting to decrease from $800 million in 2008 to $729 million in 2018 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Among the agents losing patent protection over the next few years, generic erosion of Merck's Integrilin will likely be the most significant, with sales expected to decline by about $100 million from 2008 to 2018. But Merck is expected to recoup some of these losses with the 2011 launch of its adenosine agonist, Acadesine, which is expected to be the first agent to receive regulatory approval for reperfusion injury.

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

- The launches of several oral fixed-dose anticoagulants are expected to spur a sharp increase in the atrial fibrillation drug market from $790 million in 2008 to $6.1 billion in 2018 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Growth will be driven by sales of the antiarrhythmic agent dronedarone (Sanofi-Aventis's Multaq), which is expected to account for 11% of total atrial fibrillation patient share and generate sales of $660 million in 2018.

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

- Generic erosion of levofloxacin, moxifloxacin, and piperacillin/tazobactam is expected to fuel a 1.6% annual decline in sales of antibiotics to treat community-acquired pneumonia. As a result, the market will decrease from more than $850 million in 2008 to more than $720 million in 2018, in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Although patent expirations in both the inpatient and outpatient settings will constrain the market, the launch of several new agents in the inpatient setting will help to partially offset losses in the overall market.

Source: Decision Resources, Pharmacor report on Community-Acquired Pneumonia. For more information, visit decisionresources.com.

- The fixed dose co-formulation of Tibotec's rilpivirine and Gilead's Truvada is forecast to achieve sales of more than $2 billion in the HIV drug market in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Its efficacy and favorable side effect profile are expected to make rilpivirine/Truvada a key successor to the HIV market leader, Bristol-Myers Squibb/Gilead's Atripla, a combination of efavirenz, tenofovir, and emtricitabine that recorded more than $1.5 billion in sales in 2008. Interviewed experts indicate that the major drawbacks of Atripla are the neuropsychiatric and lipid side effects of the agent's efavirenz component.

Source: Decision Resources, Pharmacor report on Human Immunodeficiency Virus. For more information, visit decisionresources.com.

- While regulatory approval for Amgen's Prolia in the European Union appears imminent, the Food and Drug Administration has recommended postmarketing surveillance of the agent in the United States due to concerns about an increased risk for infections and malignancy observed in Phase III clinical trials. Despite this surveillance, Prolia is expected to garner robust sales of $1.1 billion in 2018 in the world's major markets.

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

- Generic erosion of several established branded atypical antipsychotics is expected to contribute to a decline in the schizophrenia drug market, from $6.3 billion in 2008 to $5.2 billion in 2013 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. But the subsequent uptake of emerging therapies, primarily depot formulations, will likely cause the market to stage a

modest recovery over the five years from 2013, reaching $5.6 billion in 2018.

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

- Bristol-Myers Squibb/AstraZeneca's Type 2 diabetes drug Onglyza is forecast to generate peak-year blockbuster sales of more than $1 billion in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Although it does not offer significant clinical benefit over rival DPP-IV inhibitor Merck's Januvia, the update of Onglyza will likely be driven by its safety and tolerability, convenient administration, and the lack of weight gain associated with its use.

Source: Decision Resources, Pharmacor report on Type 2 Diabetes. For more information, visit decisionresources.com.

- Despite not having a HER2 (human epidermal growth factor receptor-2) status label restriction in Europe, most surveyed oncologists reserve Genentech's Avastin for HER2-negative patients, particularly for patients with triple negative breast cancer. In the surveyed European countries where Avastin is reimbursed, the drug is used in between 16% and 38% of first-line metastatic breast cancer patients, and between 8% and 27% of second-line metastatic breast cancer patients. Through 2010, Avastin's patient share will increase to between 25% and 35% in the first-line treatment setting and between 17% and 36% in the second-line setting. This equates to a potential 30% increase in Avastin sales over the next 12 months.

Source: Decision Resources, Physician & Payer Forum -- European Trends in Targeted Therapies in Breast Cancer: A Clinician and Payer Perspective on the Current and Future Uptake. For more information, visit decisionresources.com.

- According to responses from surveyed dermatologists, Centocor Ortho Biotech/Janssen-Cilag's Stelara and Abbott's briakinumab, both interleukin inhibitors, will capture 22% of the biologics share of the market for moderate-to-severe psoriasis drugs in 2012. Among these two agents, Stelara will experience greater uptake, capturing nearly three times as much patient share as briakinumab. By the end of 2012, surveyed physicians expect to use Stelara in 16% of biologics-treated patients with moderate-to-severe psoriasis.

Source: Decision Resources, Physician & Payer Forum — The Next Wave of Psoriasis Biologics: Physician and Payer Perspectives on Novel Interleukin Inhibitors. For more information, visit decisionresources.com.

- In the near future, the European lifestyle disorders therapeutics market is set to witness enhanced therapies and novel drugs to treat such conditions and reduce the risk of co-morbidities. The European obesity therapy market is expected to grow from $668.1 million in 2008 to almost $1.16 billion in 2015, while the European market for erectile dysfunction therapies is expected to increase from $1.23 billion in 2008 to almost $2.17 billion in 2015.

Source: Frost & Sullivan, European Lifestyle Disorders Therapeutics Market. For more information, visit pharma.frost.com.

- With the introduction of newer dopamine agonists, as well as fresh recommendations and treatment guidelines that call for using dopamine agonists as a first-line therapy, the European Union (EU) market for Parkinson's disease is experiencing a shift away from the use of carbidopa/levodopa. The EU market generated revenue of more than $1.28 billion in 2008 and is forecast to reach $2.28 billion in 2015.

Source: Frost & Sullivan, European Markets for Parkinson's Disease Therapeutics. For more information, visit pharma.frost.com.

- The U.S. government's HITECH incentives can encourage physicians to buy electronic medical record (EMR) systems, but it is the vendors and hospitals that affiliate with physicians that will ultimately determine if they go electronic. The EMR market is projected to come in at $13.8 billion for 2009, which is not up to its full potential. Solo practicing or small group practice-based physicians have fewer savings to reap than large healthcare systems, but the change in their workflow will likely reduce short-term productivity when they make the switch.

Source: Kalorama Information, EMR 2010 (Market Analysis, ARRA Incentives, Key Players, and Important Trends). For more information, visit kaloramainformation.com.

- Cardiac marker POC tests are now widely used in hospitals and have emerged as a successful model of the concept of point-of-care diagnostics. The world market for POC cardiac enzymes and tests has been growing at 12% a year for the past three years and was estimated at $490 million in 2008.

Source: Kalorama Information, Point of Care Diagnostics 2010 and Beyond: Rapid Testing at a Crossroads. For more information, visit kaloramainformation.com.

- Government healthcare reforms supported rapid expansion of the Chinese drug-eluting stent market in 2009, and initiatives undertaken by the Chinese government are expected to continue to drive the market to a value of more than $900 million by 2014, for an average growth rate of almost 20% over the next five years.

Source: Millennium Research Group, Asia Pacific Markets for Interventional Cardiology Devices 2010. For more information, visit mrg.net.