

INFECTIOUS DISEASE KEY FINDINGS

- Drug development, vaccine development, and novel approaches to therapeutics are urgently needed for bacterial, viral, fungal, and prion diseases, which cause high morbidity and mortality in both the developing and the developed world.
- Drug resistance, emerging infections, and the threat of bioterrorism make the understanding of virulence factors and disease pathogenesis essential to form a springboard from which to launch drug discovery programs.
- Genomics is being applied to drug discovery across the spectrum of infectious diseases, whether they are caused by bacteria, viruses, fungi, parasites, or prions. Genomic data can be used in public health surveillance and monitoring of infectious diseases, particularly when there is a threat of a pandemic or bioterrorist attack.
- Developing countries have great incentives to explore natural sources in drug development, the major ones being to develop better anti-infectives against tropical diseases and to benefit from the revenue from drug sales.

Source: Business Insights, Innovations in Combating Infectious Diseases. For more information, visit global-businessinsights.com.

TOP SIX POSTLAUNCH MSL ACTIVITIES How involved are your field-based medical specialists in supporting the following tactics postlaunch? Companies very involved Companies somewhat involved Companies not involved Identify, develop, and maintain 78% 11% 11% relationships with thought leaders Competitive intelligence 75% 25% Provide feedback to marketing 62% 21% personnel on product perceptions Identify and interact with 35% 50% 15% national societies and organizations 43% 39% 18% Product attribute shaping Speaker training 41% 34% Source: Best Practices, Medical Science Liaisons: Gaining Access and Forging Relationships with Key Opinion Leaders. For more information, visit best-in-class.com.

Accurate, Rapid Diagnosis Key to Developing Effective INFECTIOUS DISEASE THERAPIES

Despite significant breakthroughs in the past century of development of antibiotic, antiviral, and antiparasitic drugs and vaccines, the eradication or even control of many infectious diseases has not yet been accomplished. Of particular current concern are the problems of rapidly developing drug resistance, emerging and re-emerging diseases, the threat of bioterrorism, and the speed of reaction to the appearance of virulent strains posing pandemic threats.

According to a recent Business Insights report, Innovations in Combating Infectious Diseases, the key to developing successful drugs and vaccines against this new batch of infectious threats is to understand the pathogenic process and gain insight into where and how it can best be interrupted. In addition, the effective treatment of infectious diseases is dependent on accurate and rapid diagnosis, and this in itself can present significant challenges, especially in cases where the disease progression is poorly understood or has long, asymptomatic latency.

For more information, visit globalbusinessin-sights.com.

MSLs Are Increasingly Important for **THOUGHT LEADER RELATIONSHIPS**

Pharmaceutical and biotechnology organizations are discovering that medical science liaisons (MSLs) are not only more likely than traditional sales representatives to gain access to key opinion lead-

ers (KOLs) and physicians, but that the science background of MSLs enables them to have these critical conversations within the necessary tight time frames.

A recent report by Best Practices, Medical Science Liaisons: Gaining Access and Forging Relationships with Key Opinion Leaders, found that, contrary to industry belief, 89% of companies surveyed do not reduce the number of their field-based medical specialists after a product has been launched, since forging thought leader relationships takes time and is an essential tool for understanding and competing in the marketplace.

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

Pharma Companies Increasing Outsource MANUFACTURING, SUPPLY CHAIN IT

Life-sciences companies are increasingly using third-party outsourcing firms to augment and/or replace varying aspects of their IT responsibilities, with continued growth in spending on these services expected over the next 12 months.

A recent IDC Health Insights report, Vendor Assessment: Life Science Buyers Guide to Manufacturing and Supply Chain IT Outsourcing, found that 63% of pharmaceutical companies have outsourced at least some aspects of manufacturing or supply chain-related IT, up from 48% in 2008.

According to the report, industry sentiment and adoption trends all point to continued growth in IT outsourcing of between 4% and 6% over the next 12 to 18 months, followed by moderate growth of about 4% annually for the next two to three years. For more information, visit idc-hi.com.

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QUICK FACTS

The global market for cardiovascular therapeutic drugs is estimated to be worth \$144 billion in 2010, but is expected to decrease to less than \$140 billion in 2015, for a compound annual growth rate (CAGR) of -0.7%. Projected declines in the hypertension and hyperlipidemia categories will be partially offset by 2.2% CAGR in the thrombosis segment and 11% CAGR in the cardiac failure segment.

Source: BCC Research, Cardiovascular Therapeutic Drugs: Technologies and Global Markets. For more information, visit bccresearch.com

The global market value for diabetes therapies and diagnostics is estimated to come in at \$38 billion for 2010 and to increase to \$51.2 billion in 2015, for a five-year CAGR of 6.1%. The largest segment of the market, insulin products (including administration devices), is expected to be worth \$16.4 billion in 2010 and to reach \$22 billion in 2015.

Source: BCC Research, Diabetes Therapies and Diagnostics. For more information, visit bccresearch.com.

headlines last year are now in the critical postintegration period, and while it's too early for final verdicts, one M&A issue that continues to create problems for the industry is integration of corporate cultures. Among M&A partners surveyed, 59% rated their integration projects as effective and 11% rated efforts as extremely effective. But participants also recognized the challenges of the M&A process, noting that successful integration requires intensive planning and diligent execution.

Source: Best Practices, M&A Integration Excellence: What Bio-Pharma Companies Need to Know. For more information, visit best-in-class.com.

The two most important factors that biopharmaceutical companies consider as they build their medical science liaison (MSL) and other field-based medical teams are the number of thought leader relationships and the number of supported brands. Among 50 surveyed life-sciences companies of all sizes, 74% and 72% of survey respondents identified number of supported brands/products and number of thought leader relationships, respectively, as key criteria for determining the size of an MSL team.

Source: Cutting Edge Information, Best Practices in MSL Team Management: Benchmarks for Team Staffing, Budgets and Structure. For more information, visit cuttingedgeinfo.com.

Pharmacoeconomics spending is projected to increase by 8% this year in the United States; about 66% of surveyed respondents across all

life-sciences sectors reported having higher spending levels, while 27% expected spending to stay the same and only 7% reported a decrease. Health economics spending in Europe and Canada increased 21%, and emerging mar-

kets have seen a 45% increase in funding. Source: Cutting Edge Information, Health Economics and Outcomes Research: U.S., Europe, Canada and Emerging Markets. For more information, visit cuttingedgeinfo.com.

Generic erosion is set to shrink the allergic rhinitis market, which is expected to post a 20% decline in sales value over the next 10 years despite a marginal increase in sales volume. Disease-specific drug sales for allergic rhinitis came in at \$5 billion in the seven major markets in 2009 and are forecast to drop to \$4 billion in 2019 as a result of the entrance of cheaper generics following patent expiries, most notably in the United States.

Source: Datamonitor, Allergic Rhinitis: Opportunities in a declining market. For more information, visit datamonitor.com.

When U.S. payers were asked about substitution of biosimilars for branded biologics at the pharmacy level, about 48% agreed that it was a good idea. But most surveyed U.S. payers believe that while biosimilars are similar to reference biologics, biosimilars are not identical and may have significant clinical differences with their reference products.

Source: Decision Resources, Biosimilars Advisory Service: U.S. and EU Payer Perspectives. For more information, visit decisionresources.com.

In 2014, sales of drugs from multinational corporations are forecast to represent 92% of Mexico's non-small-cell lung cancer drug market. Factors promoting the market's growth include a modest increase in the use of premium-priced chemotherapies and targeted agents, brand loyalty among prescribing oncologists, and an increase in diagnosed incident cases.

Source: Decision Resources, Emerging Markets report, Non-Small-Cell Lung Cancer in Mexico. For more information, visit decisionresources.com.

The launch of several high-priced novel disease-modifying therapies, including the first oral agents approved for the indication, coupled with increasing use of current and emerging monoclonal antibodies, is expected to fuel a modest 3% annual growth in the multiple sclerosis (MS) drug market through 2019. Despite safety concerns with both of the anticipated first-to-market oral drugs for MS, Novartis/Mitsubishi Tanabe Pharma's FTY-720 (Gilenia) and Merck Serono/EMD Serono's oral

cladribine, combined sales of the agents are anticipated to exceed \$2 billion in 2019 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

Source: Decision Resources, Pharmacor 2010 findings on Multiple Sclerosis. For more information, visit decisionresources.com.

The launch and uptake of nine emerging therapies is expected to drive the prostate cancer drug market to more than double from nearly \$4 billion in 2009 to \$8.4 billion in 2019 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Sales of emerging therapies, most notably Dendreon's Provenge, will likely account for about 57% of the total prostate cancer market in 2019.

Source: Decision Resources, Pharmacor 2010 findings on Prostate Cancer. For more information, visit decision resources.com.

Continued uptake of marketed and emerging interleukin and TNF-alpha inhibitors and a twofold increase in the penetration of biologics in the moderate-to-severe population will drive the psoriasis drug market to double from \$3.4 billion in 2009 to \$6.8 billion in 2019 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. While Amgen/GlaxoSmithKline/Pfizer/Takeda's Enbrel maintained its market dominance in 2009, earning \$1.3 billion in sales, it will face stiff competition from Abbott/Eisai's Humira and the interleukin inhibitors in the coming years.

Source: Decision Resources, Pharmacor 2010 findings on Psoriasis. For more information, visit decisionresources.com.

In the rheumatoid arthritis (RA) drug market, the uptake of alternative biologics such as Roche/Chugai's Actemra/RoActemra is expected to erode the market share of TNF-alpha inhibitors over the next decade. Actemra/RoActemra is forecast to emerge as the likely preferred biologic agent for TNF-refractory RA patients and garner blockbuster sales of about \$1.5 billion in 2019 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. While TNF-alpha inhibitors such as Amgen/Pfizer/Takeda's Enbrel and Abbott/ Eisai's Humira will continue to dominate RA treatment, the market share of TNF-alpha inhibitors is projected to decrease from 75% in 2009 to 58% in 2019.

Source: Decision Resources, Pharmacor 2010 findings on Rheumatoid Arthritis. For more information, visit decisionresources.com.

After peaking at \$6.3 billion in 2011, the schizophrenia drug market is projected to decline to \$5.2 billion in 2019, because of the loss of patent protection for most atypical antipsychotics on the market. The generic erosion of key agents, most notably Lilly's Zyprexa and AstraZeneca/Astellas' Seroquel, is expected to constrain market sales over the next decade in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

Source: Decision Resources, Pharmacor 2010 findings on Schizophrenia. For more information, visit decisionresources.com.

Because of the generic erosion of key agents such as Pfizer's Effexor XR, Lilly/Boehringer Ingelheim's Cymbalta/Xeristar, and Forest Laboratories/Lundbeck's Lexapro/Cipralex/Seroplex, the unipolar depression drug market will likely shrink by roughly 10% over the next decade in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Sales of therapies in the unipolar depression market which includes those attributed to major depressive disorder, dysthymia, and minor depression — are expected to decline to just over \$9 billion in 2019 in the countries under study. Although generic erosion will constrain overall growth, sales of atypical antipsychotics such as Bristol-Myers Squibb/Otsuka's Abilify and AstraZeneca's Seroquel will help to partially offset the market's decline.

Source: Decision Resources, Pharmacor 2010 findings on Unipolar Depression. For more information, visit decision resources.com.

In first- and second-line treatment of Clostridium difficile infection (CDI), almost 70% of surveyed infectious disease specialists and internists say they will use Optimer's fidaxomicin, and roughly half will use Medarex/Merck's CDA1 and CDB1, one year after the launch of these agents. The lower recurrent/relapse rate associated with fidaxomicin and CDA1/CDB1 is the most influential attribute surveyed clinicians cite in their decisions to prescribe these emerging agents for

Source: Decision Resources, Physician & Payer Forum report, Hospital Anti-Infectives: Insights on the Uptake and Formulary Inclusion of Emerging Antibiotics and Antifungals: A Survey of Infectious Disease Specialists, Internists and P&T Committee Members. For more information, visit decisionresources.com.

Because of the decrease in the rollout of blockbuster drugs in recent years, the focus has intensified on the development of in silico screening systems to help shorten the time to market for new drugs. The cost of in silico drug discovery products varies according to the applications for which they are deployed, with about 50% to 90% of the cash outflow channeled toward the key steps of algorithm development, proof of concept studies, and formulation of the final application.

Source: Frost & Sullivan, Bioinformatics in Drug Discovery. For more information, visit frost.com.

The HIV/AIDS market was worth \$12 billion in 2009 and is expected to grow at a CAGR of 2% for the next seven years to reach \$13.7 billion by 2016. The global HIV infection market will continue to grow between 2009 and 2016 at a slower rate because of a series of patent expiries during this period.

Source: GlobalData report, HIV-AIDS - Pipeline Assessment and Market Forecasts to 2016. For more information, visit

The onset of a global recession did not immediately impact funding levels for biomedical HIV prevention research, with total funding for 2009 remaining stable at about \$1.165 billion for preventive vaccines, microbicides, pre-exposure prophylaxis (PrEP) and operations research related to male circumcision. But as current funding commitments come to an end, the concern is whether funders will be able to renew commitments at existing funding levels. Flat funding of HIV prevention research could have serious consequences for the field as results from critical prevention trials move the research agenda forward, and researchers could have insufficient resources to advance important opportunities to prevent HIV.

Source: HIV Vaccines and Microbicides Resource Tracking Working Group, Advancing the Science in a Time of Fiscal Constraint: Funding for HIV Prevention Technologies in 2009. For more information, visit hivresourcetracking.org.

Sysmex of Kobe, Japan, and Fullerton, Califbased Beckman Coulter lead the hematology IVD market with aggressive marketing and loyal home-country customers giving the former company a tiny edge in 2009. These two companies made up more than half of the estimated \$2 billion-plus market for tests of peripheral blood and bone marrow cells.

Source: Kalorama Information, The Worldwide Market for In Vitro Diagnostic Tests, Seventh Edition. For more information, visit kaloramainformation.com.

Vaccines continue to be the success story for

pharmaceutical companies, with the world market for preventive vaccines totaling \$22.1 billion in 2009, up from \$19 billion in 2008. The worldwide vaccine market is predicted to post a CAGR of 9.7% during the next five years, as new product introductions continue and the use of current products expand further.

Source: Kalorama Information, Vaccines 2010: World Market Analysis, Key Players, and Critical Trends in a Fast-Changing Industry. For more information, visit <u>kaloramainfor</u>mation.com.

A robust over-the-counter (OTC) drug market exists in less developed regions, where OTC is often the most practical distribution method. The OTC drug market in Asia-Pacific and Africa is worth \$21 billion with an average growth of 4% annually. In 2009, the OTC drug market in the developing BRIC nations (Brazil, Russia, India, and China) claimed a higher percentage of total pharmaceutical sales compared with more developed nations such as the United States, which had an OTC market share of 8%. India paced the quartet of burgeoning world powers with an OTC market share of 33%. China (23%), Russia (19%), and Brazil (17%) followed suit with double-digit OTC share claims.

Source: Kalorama Information, The Worldwide Over-the-Counter (OTC) Drug Market. For more information, visit kaloramainformation.com.

■ The need to reduce hospital costs is driving sales of new wound care products, and even advanced products with a higher price tag and innovations such as biotechnology, biomaterials, and tissue engineering are expected to continue to boost revenue. The worldwide wound care market posted estimated revenue of \$14 billion in 2009, and the market is expected to post annual growth of more than 6% for the next few years.

Source: Kalorama Information, World Wound Care Markets 2010. For more information, visit kaloramainformation.com.

■ The global bioinformatics market is expected to reach \$8.3 billion by 2014 at a strong CAGR of 25% from 2009 to 2014. While knowledge management formed the largest submarket in 2009 at \$1.3 billion, the bioinformatics platforms market is expected to have greatest market share in 2014 at an estimated \$3.9 billion because of rising demand from the United States and Europe.

Source: MarketsandMarkets, Bioinformatics Market -Advanced Technologies, Global Forecast and Winning Imperatives (2009-2014). For more information, visit marketsandmarkets.com.

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Survey Reveals Complex Relationship Between ENGAGEMENT AND HEALTH LITERACY

Consumer engagement is at the forefront of many initiatives to get individuals to take responsibility for their care, and health literacy is a critical component of getting these consumers engaged.

According to data from DSS Research's Healthcare Engagement Index, literacy is highly correlated with demographic characteristics such as education, income, and ethnicity, as well as attitudes about healthcare and current health status.

But consumer engagement is more correlated with measures of confidence in reading and understanding health-related information than it is with more typical literacy measures related to reported problems or difficulties using health information and materials.

Having the skills to read labels, interpret charts, and make mathematical calculations does not ensure that an individual is capable and comfortable interpreting verbal and written communications from healthcare providers and health insurance organizations.

Only the most engaged consumers exhibit the levels of health literacy and healthcare knowledge necessary to navigate the complex healthcare system and follow all the recommended healthy behaviors. Health literacy is a necessary building block, but not sufficient in itself to ensure consumer engagement.

For more information, visit dssresearch.com.





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