



Specialty Drugs

TRENDING NOW: Payer approaches to specialty drugs reveal innovation and experimentation as payers navigate this dynamic healthcare marketplace.

nsuring the appropriate use of specialty drugs is a major priority for health plans today and will become increasingly important for their future growth over the next three to five years. This is the finding of a recent study conducted by Avalere Health and commissioned by Janssen Biotech and Johnson and Johnson Health Care Systems.

The study finds there is a significant variety between what the three health plan categories — national, regional, integrated systems (IDS) — view as emerging opportunity areas in this field, with 90 respondents engaging in more than 800 activities to manage appropriate use and costs associated with specialty drug utilization.



"The greatest impact on the drug and managed care industries is that this report shines a spotlight on the need for collaboration across stakeholders," says John Unger, group product director, payer marketing, at Janssen Biotech. "For example, certain drug distributors must play a role in the creation of alternate, lower cost sites of care; and network physicians must play a role in the creation and successful implementation of treatment pathways. Successful appropriate use and cost management programs can only be realized by payers when the interdependencies across multiple stakeholders are leveraged. While the debate on healthcare costs will continue, the solutions are much more holistic, and clearly beyond unit cost management."

Other findings include:

- » National plans perceive opportunity areas to be more mature than other plans.
- » When examining delivery system changes, site-of-care optimization; medication adherence, innovative contracting arrangements, and design benefit and utilization management, national plans nearly all report progress in the integration of these areas into special pharmaceutical management practices.
- » Payers are seeing delivery system changes as an area of investment; 45% of national plans report them as established with regional and IDS plans reporting them as emerging at a rate of 93% and 94% respectively.
- **»** 92% of national plans see this as an emerging opportunity area while 60% of IDS plans report these changes as established.
- » Many stakeholders view internal and external collaboration as imperative for program
- » Accountable care organization participation is more common among national plans and IDS plans than among regional plans.
- **»** 95% of national plans and 93% of IDS plans indicate they are prioritizing IT infrastructure, but only 30% of regional plans report active investment in IT.
- **▼** For more information, visit avalerehealth.net.

mHealth to see

The world mobile health market will reap revenue of \$2 billion in 2013, according to a new visiongain report. For the healthcare industry, mobile devices represent a disruptive technology that holds the potential to transform every element of healthcare. While currently in its infancy, mHealth over the next five years will reach a rapid growth phase, visiongain analysts say. 2013 marks an entry point for any potential ecosystem members to devise their mHealth solution and position themselves to reap majority shares of mHealth revenue.

The potential benefits of mHealth solutions include improving healthcare system processes, collecting and retrieving crucial medical data and patients being able to manage chronic conditions better. Dedicated devices that perform medical functions can utilise mobile technologies such as the cloud allowing data to be uploaded and downloaded instantly. The app ecosystem also offers a vast array of programs that cover everything from general wellness to chronic diseases and illnesses.

For more information, visit visiongain.com.

Physicians Find Technology IMPLEMENTATION CHALLENGING

Adoption and optimal utilization of health information technologies (HIT) in medical practices remains problematic for the majority of U.S. physicians, according to a recent survey by the Deloitte Center for Health Solutions. The survey results show a digital divide among physicians: the adopters and non-adopters. In general, adopters are optimistic that HIT may lead to better care and lower administrative costs, while non-adopters remain concerned about implementation and operational costs in the face of seeing little ROI from HIT, such as EHR.

Deloitte expects forces within the health system to continue to push for adoption — from consumers to legislation (e.g., HITECH Act 2009) to healthcare reform-related programs (e.g., account-

THERAPEUTIC FAST TRAX...



AUTOIMMUNE DISORDERS

2012 rheumatoid arthritis (RA) drug sales in Australia were \$601.7 million. By the end of the forecast period, sales will grow to more than \$834.6 million with a CAGR of 3.0%, which includes new pipeline therapies and the launch of biosimilars. This growth will be driven by the approval/launch of Pfizer's tofacitinib and the launch of other novel products, such as Eli Lilly's anti-BAFF, tabalumab and Rigel/AstraZeneca's SYK inhibitor, fostamatinib. The uptake of biosimilars for the market leading TNF inhibitors and the growth of the aging population will also positively affect the

Source: Global Data, Rheumatoid Arthritis in Australia - Drug Forecast and Market Analysis - Event-Driven Update

▼ For more information, visit globaldata.com.

The world rheumatoid arthritis (RA) drug market will generate revenue of \$38.5 billion in 2017. The overall market for RA drugs will expand during the first half of the forecast period, although with declining annual growth. That revenue expansion is limited by the patent expiry of the leading NSAID, Celebrex, as well as increasing competition and market saturation.

In addition, the world rheumatoid arthritis medicines market will have negative growth from 2018 to 2023, as a result of patent expiry of the leading biologic drugs and competition from biosimilars (followon biologics).

Source: visiongain, Rheumatoid Arthritis (RA): World Drug Market 2013-2023

For more information, visit visiongain.com.

CANCER

The pancreatic cancer therapy market will nearly double to \$1.3 billion in 2022, due to the launch and rapid uptake of three high-priced agents — Celgene/Taiho's Abraxane, Onconova Therapeutics/Baxter International/SymBio Pharmaceuticals' Estybon and Merrimack Pharmaceuticals' MM-398 (a novel formulation of irinotecan). Even though these agents do not substantially improve the overall survival of pancreatic cancer patients, they will have a significant impact on current treatment.

Source: Decision Resources, Pharmacor Pancreatic Cancer

For more information visit decisionresources.com.

Clinical success rates for new cancer drugs doubled between the mid-1990s to the early 2000s, while the number of new cancer drugs entering clinical testing

increased 50% during the same time. Clinical success rates, which reflect the share of investigational new compounds entering clinical testing that eventually obtain marketing approval from the U.S. Food and Drug Administration, rose from 9.9% in the mid-1990s to 19.8% in the early-2000s. The clinical success rate for new cancer drugs entering clinical testing over the entire study period was

Source: Tufts Center for the Study of Drug Development

▼ For more information, visit csdd@tufts.edu.

CENTRAL NERVOUS SYSTEM

The global central nervous system (CNS) biomarker market was valued at nearly \$2 billion in 2012. The market is projected to reach nearly \$5.1 billion in 2017 after increasing at a five-year compound annual growth rate (CAGR) of 20.7%.

This aggressive growth rate is driven by several factors, including the increase in public-private partnerships with government support, pressure to keep healthcare costs down, an increasing elderly population, and the rapid advancement of genomic and proteomic technologies, which have impacted the CNS biomarker diagnostics area.

The CNS molecular diagnostic market is expected to see the greatest growth, increasing from \$196 million in 2012 to nearly \$1.5 billion by 2017 at a CAGR of 49.6%.

Source: BCC Research, Central Nervous System (CNS) Biomarkers: Technologies and Global Markets

For more information, visit bccresearch.com.

Surveyed neurologists and primary care physicians (PCPs) expect to more than double their use of Allergan's prophylactic migraine treatment Botox in the next year. Nevertheless, patient share for Botox will remain modest, because the drug is typically relegated to later lines of therapy. The increased use of Botox will also be aided by anticipated improvements in its formulary coverage. The report also finds that while more than half of surveyed physicians' acute-drug treated migraine patients receive triptans, they consider one-fifth of their episodic migraine patients and one-quarter of their chronic migraine patients to be triptan non-respond

Source: Decision Resources The U.S. Physician & Paver Forum. Evolving U.S. Market Access and Clinical Practice in the Era of Generic Triptans, Innovative Reformulations, and Botox

For more information visit decisionresources.com.

New market entrants are set to defend the neu-

rodegenerative diseases market from the looming patent cliff, leading global market revenue to increase from \$8.8 billion in 2012 to \$11 billion in 2018.

At least one Phase III pipeline candidate per condition has been developed to treat Alzheimer's disease (AD), Parkinson's disease (PD), Huntington's disease (HD) and amyotrophic lateral sclerosis (ALS) — all chronic, progressive diseases characterized by the gradual and permanent loss of neurons.

Source: GBI Research, Neurodegenerative Diseases Market to 2018 -New Product Entries in Both Niche and Broader Parkinson's Disease Treatment will Boost Market Despite Patent Cliff

For more information, visit gbiresearch.com.

The Japanese epilepsy drug market was valued at about \$556 million in 2012 and is forecast to grow at a CAGR of 3.8% to 2022. Major drivers of market growth over this forecast period will include the recent launch and growth in use of blockbuster AEDs E Keppra and Lamictal. The availability and access to a universal healthcare system and low rate of generic substitution are also factors of growth.

Source: Global Data, Epilepsy in the Japan - Drug Forecast and Market Analysis to 2022

For more information, visit globaldata.com.

DIARFTES

The world market for diabetes medications will reach \$55.3 billion in 2017. The antidiabetic medicines industry generated \$35.6 billion in 2012, and its revenue will show strong growth to 2023. The analysis shows human insulins and analogues dominated the antidiabetics market in 2012.

Furthermore, that submarket will maintain dominance in the overall diabetes treatments market to 2023. Also, rapid uptake of dipeptidyl peptidase (DPP)-4 inhibitors will stimulate overall revenue growth, owing to their safety profiles and once-daily dosage regimens.

Source: visiongain, Diabetes Treatments: World Drug Market 2013-

For more information, visit visiongain.com.

GASTROINTESTINAL

Janssen/Merck/Mitsubishi Tanabe's Remicade is the market leader for the treatment of ulcerative colitis in the EU5 (France, Germany, Italy, Spain and the United Kingdom), following the approval of its first biologic competitor — another TNF-alpha inhibitor — Abb-Vie/Eisai's Humira.

According to the results of a survey conducted nearly one year after the European approval of Humira for ulcerative colitis, 69% of gastroenterologists pointed to Remicade as their most preferred biologic, while 27%

Source: BioTrends Research Group, TreatmentTrends: Ulcerative Colitis (EU

▼ For more information, bio-trends.com.

INFECTIOUS DISEASES

The global market for infectious disease diagnostic, vaccine, and treatment products is expected to grow at a compound annual growth rate (CAGR) of 7.8%. Much of the growth is being driven by emerging markets in the BRIC countries. Hepatitis products will continue to expand in areas such as India and China where infection rates are especially high. The vaccine market for infectious diseases was estimated at nearly \$19 billion in 2012, with a CAGR of 6.9%. Growth rates are led by rotavirus vaccines at a CAGR of 21.5%.

Source: BCC Research, Global Markets for Infectious Disease Treatments

▼ For more information, visit bccresearch.com.

RESPIRATORY DISEASES

About 25% of surveyed U.S. pulmonologists would prescribe Novartis' indacaterol/glycopyrronium to

their COPD patients, driven by the robust Phase III efficacy data. But indacaterol/glycopyrronium will earn a more conservative patient share, constrained in part by a late launch relative to its competitors in the United States.

Source: Decision Resources, DecisionBase 2013, Chronic Obstructive Pulmonary Disease: What Gains in Efficacy Will Be Necessary to Meet Pulmonologist and Payer Expectations for Emerging LABA/LAMAs, LABA/ICSs, and MABAs?

▼ For more information, visit decisionresources.com.

Emerging market players are employing diverse R&D strategies to gain entry in the cystitic fibrosis market. For inhaled antibiotics, the focus is on the development of new classes and formulations of inhaled antibiotics that can reduce therapy burden and improve compliance for the management of chronic lung infections.

Examples include the development of Novartis' TOBI Podhaler and Forest Laboratories' Colobreathe that reduce time of administration by more than 70%.

The approval of Vertex's Kalydeco (ivacaftor) in

2012, a CFTR modulator and the first disease-modifying drug, paved the way for this new class of therapies.

Source: Global Data, Opportunity Analyzer: Cystic Fibrosis - Opportunity Analysis and Forecasts to 2017

For more information, visit globaldata.com.

Aligned R&D strategies are imperative for attaining access to a lucrative and underserved idiopathic pulmonary fibrosis market IPF remains a hugely untapped market with little competition in the pharmaceutical arena, with the first pharmacological treatment only becoming licensed in the EU in 2011, and no FDA-approved treatment in the United States as of March 2013.

IPF has a patient population size that is commercially attractive (an estimated 73,035 patients in the U.S. and 5EU), with the scope to attain orphan drug status, enabling a potentially faster and more cost-efficient R&D program.

Source: Global Data, Opportunity Analyzer: Idiopathic Pulmonary Fibrosis - Opportunity Analysis and Forecasts to 2017

▼ For more information, visit globaldata.com

able care organizations, medical homes, bundled payments). The overall value conversation about HIT will shift from ROI to how the technologies can help physicians do their jobs better.

The survey also has found that most U.S. physicians:

- » Believe that meaningful use (MU) holds promise for improved efficiency. In particular, primary care physicians (PCPs) perceive efficiencies through faster and more accurate billing and time savings through e-prescribing. Physicians working in accountable care organizations (ACOs) recognize improved care coordination and quicker access to clinical support (guidelines, lab reports, lab tests) as principal benefits.
- Think that major barriers to EHR adoption costs and ease of operational integration should be overcome for nonadopters to meet MU Stage 1 requirements. Some remain unconvinced: close to half of non-adopters have no current plans to introduce an EHR that meets MU criteria.
- » Are slow to adopt online tools and digital health technologies in direct patient care.
- » Do not use mobile health technologies
- **▼** For more information, visit deloitte.com.

GLOBAL PROTEOMICS MARKET				
\$ in millions				
End-Use Industry	2011	2012	2017	CAGR% 2012-2017
Research	\$1,623.0	\$1,815.1	\$2,883.4	9.7
Drug discovery and development	1,530.2	1,761.0	3,766.7	6.4
Diagnostics	194.5	246.1	1,497.9	43.5
Applied	331.6	373.7	720.0	14.0
Total	3,679.3	4,195.9	8,868.0	16.1

Proteomics Market

TO GROW

The proteomics research market accounted for \$1.8 billion in 2012, 43% of the total proteomics market and is projected to grow at a compound annual growth rate (CAGR) of 9.7% to reach nearly \$2.9 billion in 2017, accounting for 32.5% of the total market, according to BCC Research. The research market consists of academic entities, research institutes, and government laboratories.

The diagnostics market is the highest growth

end-user market for proteomics. It reached \$246.1 million in 2012; it is continuing to grow at a strong CAGR of 43.5% and is expected to reach a value of nearly \$1.5 billion in 2017.

Key growth drivers for the diagnostics market include a modest but growing pipeline of proteomics-based tests; increasing acceptance of multiplexed diagnostics tests; a high discovery rate of protein biomarkers; and a strong need for automated, rapid, and less-costly tests.

▼ For more information, visit bccresearch.com.

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