



Adherence Can Lead to Healthcare Savings

TRENDING NOW: The U.S. healthcare system could avoid hundreds of millions of dollars in medical costs if medication adherence rates improved.

Drawing on data from the 2012 CVS Caremark pharmacy benefit management (PBM) book of business, the State of the States report projects potential cost-savings within each state by examining medication adherence rates and the use of generic drugs across four common health conditions: diabetes, hypertension (high blood pressure), dyslipidemia (high cholesterol), and depression. The potential cost-savings among the states range from \$19 million to \$2.1 billion based on state member characteristics, according to the **CVS Caremark 2013 State of the States: Adherence Report**.

“These data offer policymakers and the healthcare industry a new look at adherence across geography, health condition, and prescription insurance status and demonstrates the need for increased adoption of interventions that can improve medication adherence in order to advance health outcomes for patients and lessen the cost burden for the healthcare system,” says Troyen Brennan, M.D., executive VP and chief medical officer of CVS Caremark.

Medication nonadherence in the United States accounts for up to \$290 billion in excess healthcare costs annually. Research shows that interventions such as pharmacist counseling are cost-effective and contribute to improved adherence behavior, highlighting the central role that pharmacists and other healthcare professionals can play in helping patients effectively manage chronic diseases. This is demonstrated by the CVS Caremark Pharmacy Advisor counseling program, which provides customized counseling to patients and has been shown to increase adherence rates up to 3.9% and return \$3 in savings for every \$1 spent on counseling.

For more information, visit cvscaremarkfyi.com.



Troyen Brennan

TRENDS IN ADHERENCE

- » Across all market segments (health plans, employer-sponsored plans and Medicare Part D plans), patients with depression generally had the lowest adherence rates, while patients with hypertension were most adherent.
- » Medicare beneficiaries had the highest adherence rates across the three groups.
- » Ninety-day dispensing rates were generally highest among members of employer-sponsored plans.
- » Regional variations were apparent across the groups. The lowest adherence rates for health plan members with diabetes and depression occurred in the Midwest, while the lowest rates for patients with any condition in employer-sponsored plans and Medicare Part D occurred in the South.

Source: CVS Caremark 2013 State of the States: Adherence Report

Patient Adherence Through MOBILE CHANNELS

Pharmaceutical companies allocated an average of 47% of their mobile technology budgets to patient adherence reminder calls in 2012, according to a benchmarking study by Cutting Edge Information.

The study, Patient Adherence and Compliance: Improving Outcomes through Patient Engagement Programs, found that companies allocated another 29% of the average mobile budget to text messaging, not including reminder texts. Only 11% of the average surveyed company's budget went to mobile adherence apps.

Surveyed companies mostly expected reminder calls to see spending growth between



Michelle Vitko

2011 and 2012 budgets. Indeed, 60% of surveyed companies expect to see spending increase for reminder calls. Meanwhile, 40% expect refill and dosing reminder text messages spending to decrease.

Although simple calls and texts dominated mobile adherence spending in 2011, companies also expected to see mobile spending to shift toward smartphone-rich content and delivery. One-quarter of surveyed drug companies expected to see mobile app spending grow.

“Many mobile apps are now focused on medical education, physical biometric data collection and health outcomes management,” says Michelle Vitko, senior research analyst at Cutting Edge Information. “In the coming years, the dedicated mobile adherence budget is expected to rise significantly, perhaps to as much as one-third of the mobile adherence spend.”

For more information, visit cuttingedgeinfo.com.

Drug-Diagnostic Combination STRATEGIES EXPLORED

The drug-CDx co-development model is increasingly being adopted by pharmaceutical companies as the trend toward targeted therapies gains momentum, according to FirstWord. Collaborations between pharmaceutical and diagnostics companies need to consider not only the development of the CDx but preparation for commercialization so that the appropriate test is available when the drug is approved and does not impede uptake of the drug. Market access strategies for the drug-CDx must be coordinated and not approached as separate activities.

At the same time, the disparate reimbursement systems across targeted therapies within different countries for CDx present a complex landscape, hampering market access for tests. Not only are diagnostic reimbursement systems managed ac-

THERAPEUTIC TRAX... 

AUTOIMMUNE DISORDERS

GSK's Benlysta (belimumab) was forecast to be a blockbuster therapeutic by 2014, after its 2011 approval made it the first drug to be approved for systemic lupus erythematosus (SLE) in more than 50 years, but it captured only \$106 million in 2012. But GSK still holds hope that Benlysta can become a blockbuster drug, making big clinical research investments to evaluate the drug for use in SLE patients with lupus nephritis (LN), and eight other indications including myasthenia gravis, vasculitis, and kidney transplantation. UCB's epratuzumab may be the most promising pipeline drug for SLE treatment and the Phase IIb trial showed that epratuzumab demonstrated sustained improvements in the disease activity of patients with moderate-to-severe SLE.

Source: GlobalData

▼ For more information, visit globaldata.com.

CANCER

Novartis has been the CML market leader since it first launched Gleevec in 2001. In order to prevent a major loss of revenue after Gleevec's imminent patent expiry, Novartis is fighting hard to convince physicians to prescribe its second-generation TKI, Tasisign, instead. Novartis' efforts may not be enough to overcome the allure of generic imatinib. Tasisign's long patent life and Novartis' marketing expertise will enable the company to maintain its position as market leader through 2022

Source: GlobalData, Chronic Myeloid Leukemia - Global Drug Forecast and Market Analysis to 2022

▼ For more information, visit globaldata.com.

Overall, non-small cell lung cancer patients have a high level of unmet need. Over the forecast period, several pipeline candidates are expected to launch that will address these unmet needs and have a significant impact on the NSCLC treatment landscape. Acquired resistance to the EGFR inhibitors Iressa and Tarceva due to the acquisition of secondary mutations or expression of additional resistance factors such as Met, is an area of current high unmet need in the NSCLC treatment landscape. BI's second-generation EGFR tyrosine kinase inhibitor (TKI), afatinib, is expected to delay or prevent the onset of TKI resistance.

Source: GlobalData

▼ For more information, visit globaldata.com.

The global kidney cancer drugs market is expected to grow at a CAGR of 13.4% over the period 2012-2016. The companies in this market are investing heavily in R&D to develop kidney cancer drugs from biological sources because this approach can increase the efficacy of the drugs. Moreover, companies are formulating effective injection solutions that can help retain the efficacy of the drug molecule for a longer period. For instance, Pfizer is increasingly focusing on enhancing the efficacy of its kidney cancer drug Sutent.

Source: TechNavio, Global Kidney Cancer Drugs Market 2012-2016

▼ For more information, visit technavio.com.

CARDIOVASCULAR

The global chronic heart failure (CHF) therapeutics market is forecast to grow from the 2012 value of \$2.6 billion to \$4.5 billion in 2022, climbing at a CAGR of 5.7%. Following its launch scheduled for 2015, Novartis' novel combination drug LCZ-696 will rapidly dominate the global CHF therapeutics sector. Global sales of LCZ-696 are expected to reach \$1.86 billion by 2022, with an estimated 15%-20% of all CHF patients across the United States and Europe, and revenue for the first-in-class combination drug is anticipated to top \$1.6 billion.

Source: GlobalData

▼ For more information, visit globaldata.com.

The chronic heart failure (CHF) market is a mature market that has been slowly overtaken by generic drugs, and more branded products are expected to lose market exclusivity during the next few years. The major global barriers include the sparsely populated CHF pipeline and an increasing number of generic competitors in a market that is already heavily laden with generic drugs. The market entry of Novartis' LCZ-696, the first novel, branded CHF drug to enter the market in five years, will noticeably enhance the overall market size in the seven major markets to more than \$4 billion at a CAGR of 5.7% during the forecast period.

Source: GlobalData

▼ For more information, visit globaldata.com.

CNS

Although Europe trails behind the United States in terms of market revenue, ADHD therapeutics mar-

kets are expected to show strong growth, with Spain predicted to witness a CAGR of 8% over 2012-2018, beating the U.S. CAGR of 6%. European markets have not yet neared the saturation point that ADHD therapeutics are facing in the U.S., and there is an optimistic view for ambitious growth in this region. The ADHD therapeutics market across France, Germany, Italy, Spain and the UK is predicted to reach about \$182 million in 2018.

Source: GBI Research, ADHD Therapeutics Market to 2018 - New Diagnostic Parameters for Adult ADHD Offer Hope for Higher Rates of Treatment

▼ For more information, visit gbiresearch.com.

In 2011, the global amyotrophic lateral sclerosis (ALS) market was estimated at \$112 million, but this value is expected to decline at a negative CAGR of 5.7% to hit an estimated \$70 million by 2019. The ALS pipeline has a few late-stage therapies. Pipeline drugs that could potentially launch in the forecast period include Avicena's ALS-02 (2015) and Mitsubishi Tanabe's Radicut (edaravone) (Japan only, 2013). These products will expand the market, but will not transform the treatment paradigm, as they will be mainly used as add-on treatments to Rilutek. The most promising drug, Biogen's dexamipexole, was discontinued due to a lack of efficacy and improved survival in Phase III trial results. The anticipated patent expiry of Rilutek in 2013 will therefore act as a major barrier to market growth, due to the lack of any upcoming therapeutics.

Source: GlobalData, Amyotrophic Lateral Sclerosis - Analysis and Market Forecasts to 2019

▼ For more information, visit globaldata.com.

Disease-modifying therapies (DMT) for multiple sclerosis (MS) in Canada generated \$1.8 billion in 2012, and the market will increase to \$2.1 billion in 2022 at a CAGR of 1.2%. Major drivers to the growth of the MS market over the forecast period will include the anticipated launch of efficacious pipeline products, including DMTs that target the progressive MS subtypes, which will boast overall treatment rates. Full coverage of all drugs administered in hospitals, which improves patient access to IV-administered drugs is also a major driver. The most promising DMTs in the Phase III pipeline are Biogen's BG-12 and Roche's/Genentech's/Biogen's ocrelizumab.

Source: GlobalData, Multiple Sclerosis in Canada - Drug Forecast and Market Analysis to 2022

▼ For more information, visit globaldata.com.

DERMATOLOGY

Ranging from relatively mild conditions such as acne and dermatitis to more severe conditions such as lupus and melanoma, skin conditions cost the U.S. billions of dollars every year. The global dermatology market reached \$15.8 billion in 2012 and is expected to reach \$18.5 billion by 2018, registering a CAGR of 2.8%. Much of the developed world will see moderate growth due to the continuing recession, whereas more positive growth from emerging markets such as Brazil, Russia, India, and China is anticipated by 2018.

Source: BCC Research, Skin Disease Treatment Technologies and Global Markets

▼ For more information, visit bccresearch.com.

The branded melanoma market is set to grow to \$2.8 billion across the U.S. and major European markets by 2021, driven by increasing patient numbers, organic growth of key marketed drugs, and the entry of novel therapies into the melanoma market. Bristol-Myers Squibb is set to be a big winner as its promising PD-1 inhibitor, nivolumab, moves into Phase III development. With its immunotherapy Yervoy currently dominating the first-line treatment of metastatic melanoma, Bristol-Myers Squibb's share of the melanoma market is set to increase substantially over the coming years.

Source: Datamonitor Healthcare

▼ For more information, visit datamonitorhealthcare.com.

cording to national and local policies, diagnostics are reimbursed separately from targeted therapies, further adding to the complexities of commercialization of personalized medicine. Current reimbursement systems were designed to support traditional diagnostic tests, providing little room for recognizing innovation through value-based pricing.

▼ For more information, visit fwdossier.com.

Study Reveals Multiple

ROOT CAUSES FOR DRUG SHORTAGES

Drug shortages are multi-factorial, often resulting from issues within the quality systems, which can be affected by key aspects of organizational governance and the quality of interactions with regulators, according to a new report by the International Society for Pharmaceutical Engineering (ISPE). While no single technical or manufacturing cause

INFECTIONS

The hepatitis c virus (HCV) market generated about \$4.0 billion from global sales in 2012. Over the next 10 years, this market is expected to grow to reach \$10.8 billion, with major growth occurring in the main HCV markets, such the United States. Interferon-free hepatitis c virus therapies, which have improved side effect profiles compared with current therapies, will fundamentally change the HCV treatment algorithm. Gilead, AbbVie, Bristol-Myers Squibb, and Boehringer Ingelheim will introduce interferon-free therapies in the United States, European, and/or Japanese marketplaces within the next two to three years.

Source: GlobalData, PharmaPoint: Hepatitis C Virus - Global Drug Forecast and Market Analysis to 2022

▼ For more information, visit globaldata.com.

RESPIRATORY

The global chronic obstructive pulmonary disease (COPD) therapeutics market will be driven by the entry of new, more efficacious and convenient products over the coming years. Upcoming combination drugs including Novartis' QVA-149, GSK's umeclidinium bromide/vilanterol and Boehringer Ingelheim's olodaterol/tiotropium promise greater efficacy than their individual components and currently available treatments, and the continued growth of the industry will rely largely on their success.

Source: GBI Research, Chronic Obstructive Pulmonary Disease (COPD) Market to 2019 — Highly-Priced New Combination

for drug shortages was identified, the key findings include:

- » Issues within the quality systems of manufacturing can lead to drug shortages. Respondents weighted quality issues as the single most important factor leading to drug shortages. Within the quality systems, the data suggested that issues with aseptic processing equipment are a significant factor in sterile drug shortages.
- » Companies that have successfully avoided drug shortages focus on strong quality systems, and the involvement of company leadership is notable in those companies that avoid shortages. Support from senior management to drive the drug shortage prevention programs, as well as well-defined metrics tailored to proactively identify the potential risk of a shortage, adequate resources for the prevention program, and specific organizational goals to prevent shortages differentiated the companies that

Products Forecast to Capture Significant Market Share and Drive Growth

▼ For more information, visit gbiresearch.com.

In 2012, there were 135.28 million lifetime prevalent cases of asthma in the 10 major markets (U.S., France, Germany, Italy, Spain, UK, Japan, Australia, China, and India). Estimates are that there will be 159.20 million lifetime prevalent cases of asthma in the 10 major markets by 2022, with an overall growth of 17.7% over the next decade.

Source: GlobalData, EpiCast Report: Asthma - Epidemiology Forecast to 2022

▼ For more information, visit globaldata.com.

VACCINES

Sanofi's Fluzone QIV may earn as much as \$384 million in 2022, usurping the existing trivalent formulation of Fluzone as the U.S. market leader, as quadrivalent vaccines make their foray into the healthcare market this year. Sanofi received FDA approval for its supplemental biologics license application (sBLA) for Fluzone Quadrivalent on Monday, June 10, 2013. In addition to new formulations, the future of influenza vaccines also rests on the success of novel routes of administration that are able to better stimulate the innate immune system to produce a strong response to the viral antigen. This trend is expected to influence the sales of Fluzone QIV, as the vaccine will face competition from the growing use of Fluzone IntraDermal.

Source: GlobalData

▼ For more information, visit globaldata.com.

successfully avoided a shortage from those that did not.

- » Improved regulatory interaction can mitigate the likelihood of a shortage. A significant number of respondents indicated that issues related to health authority inspections and approval processes also played an important role in drug shortages. An additional differentiator of companies that successfully avoided shortages was their emphasis on building strong relationships with regulatory authorities.

▼ For more information, visit ispe.org.

Branded Biologics Sales

WILL GROW

The growing dependence on biologics to provide significant benefits in the effective treatment of chronic diseases such as rheumatoid arthritis, psoriasis, cancer, Crohn's disease, and similar condi-

tions has resulted in the continued increase in sales, generating more than \$128 billion in 2012 alone, according to GlobalData.

This trend is expected to continue in the short term, growing by a CAGR of about 5.6% to reach more than \$168 billion by 2017. Afterwards, patent expirations and the existence of clearer regulatory frameworks for biosimilars will result in an upsurge of biosimilars in key biologics markets such as the United States, having an adverse effect on global branded biologic sales. Furthermore, the uptake of biosimilars is also expected to increase in other markets outside the United States as physicians and other stakeholders get more comfortable with their substitution, capturing market share from branded biologics.

▼ For more information, visit globaldata.com.

Global Stem Cell Market to GROW

The market for stem cells was valued at \$26.23 billion in 2011 and is expected to reach an estimated value of \$119.51 billion in 2018, growing at a CAGR of 24.2% from 2012 to 2018, according to a recent report from Transparency Market Research.

The market growth is attributed to therapeutic research activities led by government support worldwide and the growing number of patients with chronic diseases across the globe. In addition, rising awareness of regenerative treatment options and growing importance of stem cell banking services are also fostering the growth of the market. Apart from these, development of medical tourism hubs in developing nations such as India

and China and in turn migration of patients from developed nations such as the United States, and Europe for quality treatment at significantly lower prices will also serve the market as a driver especially for the Asian stem cell market.

The stem cell market will be driven by a rising proportion of patients with neurological and other chronic conditions and rising disposable incomes of patients, induced by economic growth of Asian regions in the next five years. In addition, increasing dependence on stem cells for drug discovery and screening will boost the growth of the market in the future. Increased outsourcing of contract research and clinical trials to developing Asian regions will further encourage growth of the stem cell market.

▼ For more information, visit transparency-marketresearch.com.

Global Epigenetic Market to RISE

The global epigenetic drugs and diagnostic technologies market was valued at \$1.6 billion in 2011 and is estimated to reach a market worth \$5.7 billion in 2018 at a CAGR of 19.4% from 2012 to 2018, according to a recent report from Transparency Market Research.

The growth of the epigenetics market is driven by factors such as an increase in the aging population, as there is a strong correlation between cancer and aging. People aged 60 and older are more prone to cancer, and many countries are advocating early detection of cancer through screening kits (Epi ProColon, Epi ProLung), which are driving the epigenetic drugs and diagnostic technologies market.

Epigenetic drugs make it possible to reverse the aberrant gene expression, which leads to various disease states. The inhibitors, DNA methyltransferase (DNMT), and Histone Deacetylase (HDAC) are responsible for regulating the cellular expression.

Out of the two inhibitors, DNMT accounts for a larger share as these inhibitors and offers an improved access for targeting the cancerous cells. Currently, four drugs are approved by FDA and are commercially available. Two of them are DNMT inhibitors: Celgene's Vidaza (azacitidine) and Eisai's Dacogen (decitabine) for the treatment of Myelodysplastic Syndrome (MDS), and the other two are HDAC inhibitors: Merck's Zolinza (vorinostat) and Celgene's Istodax (romidepsin) both for treatment of cutaneous T cell lymphoma (CTCL).

▼ For more information, visit transparency-marketresearch.com.

Growth Expected in THE ORPHAN DRUG MARKET

The increasing incidence of diseases affecting the aged will drive the orphan drug market to increase at a rate of 11.5% throughout the forecasted period, reaching a value of \$105.2 billion by 2017, according to Kalorama Information.

Non-Hodgkin's lymphoma, multiple myeloma, renal disease, and osteoporosis are among the diseases where treatments are not sufficient, according to the report, which breaks out the market by company and by category.

▼ For more information, visit kaloramainformation.com. PV

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