



▶ *Formulary Decision Makers Want*

Digital Resources from Pharma

TRENDING NOW: As formulary decision makers become a driving force behind the products that are prescribed to patients, pharma companies are seeking to engage these stakeholders through emerging channels.

Formulary decision makers are making important P&T committee decisions with the help of websites and apps, often including those provided by pharma companies, according to the 2012 Taking the Pulse Formulary Decision Makers study from Manhattan Research. The study surveyed 205 managed care organizations (MCOs), pharmacy benefit managers (PBMs), and hospital pharmacy and therapeutic (P&T) committee members in the United States about their use of the Internet, digital information sources, and pharma-provided services and tools.

“Formulary decision makers are increasingly turning to digital resources outside of the manufacturer dossier to help them make crucial decisions about formulary placement,” says Manhattan Research President Meredith Ressi. “As formulary decision makers become a driving force behind the products that are prescribed to patients, pharma companies are seeking to engage these stakeholders through emerging channels.”

Other findings include:

- » Almost six in 10 hospital P&T committee members and more than seven in 10 MCO P&T committee members use websites or apps to support decisions on adding or removing drugs to the formulary.
- » More than four in five hospital, MCO, and PBM P&T committee members are interested in accessing information and services from pharma websites or apps to help them with their P&T committee work, such as treatment guidelines, clinical trial information, and formulary information.
- ▼ For more information, visit manhattanresearch.com.



Meredith Ressi

Nonadherence Study Highlights:

- » The U.S. pharmaceutical industry loses an estimated \$188 billion annually due to medication nonadherence. This represents 59% of the \$320 billion in total U.S. pharmaceutical revenue in 2011.
- » Global pharmaceutical revenue loss is estimated to be \$564 billion, or 59% of the \$956 billion in total global pharmaceutical revenue in 2011.
- » Medication nonadherence is a problem across almost all chronic conditions, not only for primary-care conditions such as diabetes, hypertension, and high cholesterol, but also for such serious conditions as HIV, oncology, transplant, and glaucoma.
- » In the U.S. diabetes market alone, revenue loss is estimated to be \$11.4 billion.

Source: CapGemini

“Pharmaceutical sales models are changing rapidly,” says Richard Lang, a pharmaceutical industry analyst for visiongain. “Healthcare payers have greater influence in prescribing decisions, complicating market access strategies for pharmaceutical companies.”

▼ For more information, visit visiongain.com.



Richard Lang

Companies Lose Revenue to NONADHERENCE

The estimated revenue lost by the U.S. pharmaceutical industry each year due to non-adherence to medications for chronic disease is \$188 billion, according to a recent report by Capgemini Consulting and HealthPrize Technologies. Extrapolated to the global pharmaceutical industry, revenue losses are estimated to be \$564 billion. This number is significantly higher than the \$30 billion global revenue loss often quoted to date from a 2004 study, and higher than many pharmaceutical executive estimates.

This revenue loss represents 59% of all pharmaceutical revenue, which was \$320 billion in the United States and \$956 billion globally in 2011 according to IMS, and 37% of potential total annual revenue, which would be \$508 billion in the United States and \$1.52 trillion globally.

“The revenue that pharma leaves on the table due to lack of adherence to prescription medications is much higher than usually thought,” explains Thomas Forissier, principal at Capgemini Consulting.


▼ For more information, visit capgemini-consulting.com.

Contract Sales to GROW

The global market for pharmaceutical contract sales will be worth \$3.91 billion in 2013. Between 2011 and 2017, the worldwide market is expected to grow with a CAGR of more than 8%. Demand for outsourced sales teams will drive growth during this decade. Innovation and improvements to current technology will provide greater opportunities for virtual detailing. In 2023, outsourced e-detailing will account for close to \$200 million in CSO revenue, a report from visiongain shows.

KOL Advocacy is CRITICAL

The advocacy of key opinion leaders (KOLs) has proven to be among of the most effective and critical means of building product awareness in the medical and scientific communities. But according to a recent report from Best Practices — Optimizing Key Opinion Leader Relationships: Best Practices in KOL Management — some companies are still struggling to gain traction in this critical space. More than one-third of companies profiled say KOL management efforts are not highly valued within the organization.

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

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Thought Leader Pool Shrinking as Compensation Rates Fall

TRENDING NOW: The number of thought leaders willing to provide services for pharmaceuticals may decline further as disclosure rules come into effect.

The average number of thought leaders working with large pharmaceutical companies declined in one year by 26%, according to a Cutting Edge Information study.

The study, Determining European KOL Compensation: Fair-Market Value Benchmarks, found that the aging population impacts the number of experienced professionals available to work with companies. This decline is a reflection of what the industry as a whole is facing. Having fewer relationships with thought leaders puts enormous pressure on field-based medical teams to source new candidates and to work harder than ever to keep key opinion leaders (KOLs) interacting with the company.

“The number of thought leaders willing to provide services for pharmaceuticals may decline further as disclosure rules come into effect,” says Elio Evangelista, director of operations at Cutting Edge Information. “Federal laws, new hospital, and academic regulations and disclosure requirements for publication in medical journals will likely come into effect in the coming years.”

For more information, visit cuttingedgeinfo.com.



Elio Evangelista

Big Pharma EMBRACES BIOLOGICS

Fast-evolving biopharmaceuticals will challenge synthetic market dominance in the global market for active pharmaceutical ingredients (APIs), states a new report by GBI Research.

The report — Active Pharmaceutical Ingredients (APIs) Global Market to 2017: Growth in Developing Markets to Come From Cost Efficient Manufacturing and Rising Domestic Demand — states that growth in pharmaceutical synthetics is being driven by the development of new drugs and therapies across the globe, but the biopharmaceuticals market is also starting to blossom, and can offer higher target specificity, higher efficacy, and fewer side effects than possible with synthetics.

Over the next five years, generic and biosimilar markets are expected to grow at a collective CAGR of 13.4%, in contrast to an expected collective CAGR of only 4.4% for the innovative and biologic API markets. The total revenue generated by the global API market was \$108.6 billion in 2011, which

is expected to increase at a healthy CAGR of 7.4% between 2011 and 2017 to generate expected revenue of \$167.1 billion in 2017.

For more information, visit gbiresearch.com

Other Market Insights...

Generic Market EXPECTED TO GROW

The world market for generic pharmaceuticals will reach \$127.8 billion in 2013. This is a finding of Visiongain's recent report, Generic Drugs: World Market 2013-2023.

The world prescription generic drug industry was valued at \$110.8 billion in 2011. If a more general definition of off-patent medicines is used to define generics, some estimates put the size of the industry at more than \$150 billion. In the United States, generic drug sales have more than tripled since 2000. Sales of generics currently represent more than 40% of worldwide sales, with generic

THERAPEUTIC TRAX

AUTOIMMUNE DISORDERS

Although biologic use is much lower among SLE patients compared with other immune conditions such as rheumatoid arthritis and psoriatic arthritis, rheumatologists in the United States reported they significantly increased biologic use among SLE patients in 2012, up 4% since 2011. This increase in biologic penetration in SLE patients may be due to physicians' comfort level with biologics and/or the availability of relative newcomer, GlaxoSmithKline/Human Genome Science's Benlysta (belimumab), which is the only biologic indicated for SLE giving physicians another treatment option they previously never had. Benlysta was approved by the FDA in March of last year, which is the first newly approved agent for SLE in about 50 years.

Source: BioTrends Research Group, TreatmentTrends: Lupus US

For more information, visit bio-trends.com.

CANCER

The drug market for non-small-cell lung cancer (NSCLC) will increase to more than \$6 billion in 2021, fueled largely by the entry of seven new agents. Pfizer's Xalkori will drive the NSCLC drug market to increase from \$4.6 billion in 2011. This growth will occur despite generic/biosimilar erosion of key agents used in the management of NSCLC. Sales of Lilly's Alimta, a branded drug that dominated the 2011 NSCLC market, will weaken significantly in the second half of the forecast period owing to entry of generics.

Source: Decision Resources, Pharmacor Non-Small-Cell Lung Cancer advisory

For more information, visit decisionresources.com.

Through 2021, small-molecule angiogenesis inhibitors will dominate the renal cell carcinoma (RCC) drug market. In 2011, this drug class held a 68% market share; this share will peak in 2017 at about 85%. In 2021, the market share of small-molecule angiogenesis inhibitors will fall to 75% because of the generic erosion of some therapies in this class and the launch of Bristol-Myers Squibb/Ono Pharmaceuticals' novel immunotherapy, nivolumab.

Source: Decision Resources, Pharmacor Renal Cell Carcinoma advisory

For more information, visit decisionresources.com.

In 2011, the leukemia therapeutics market for four major leukemia indications was estimated at \$4 billion, indicating a CAGR of 21.0% since 2004. The market is predicted to grow at a CAGR of 9.5% between 2011 and 2018 to reach to \$7.6 billion by 2018. Acute myelogenous leukemia (AML) therapeutics accounted for 43% of the leukemia drug development pipeline last year. But leukemia exists in four different types and 50 subtypes and diagnostic tests for leukemia are expensive and inaccurate, with around 50% of all patients misdiagnosed as per their exact subtype of the disease. Therefore achieving accurate

diagnosis remains a challenge and may prove to be a significant obstacle for the leukemia therapeutics market to overcome.

Source: GBI Research, Leukemia Therapeutics Market to 2018 — Strong Late-stage Pipeline to Sustain Branded Drugs' Major Market Share

▼ For more information, visit gbiresearch.com.

During 2011-2019, the melanoma therapeutics market is expected to record a CAGR of 16.6%, from \$800 million in 2011 to \$2.6 billion in 2019. The growth of the market is primarily due to new product approvals and an increase in incidence rates during the forecast period. There are eight first-in-class products in late-stage development, which include Abraxane, Allovectin-7, bevacizumab, GSK1120212, MAGE-A3, Masitinib, OncoVEXGM-CSF, and Tasigna. In the future, competition for advanced melanoma is set to intensify as these pipeline molecules would compete with Yervoy and Zelboraf, addressing their limitations in terms of better safety and a likely improvement in efficacy.

Source: GlobalData, Melanoma Therapeutics — Pipeline Assessment and Market Forecasts to 2019

▼ For more information, visit globaldata.com.

The major markets (the U.S., the UK, France, Germany, Italy, Spain, and Japan) for neuroendocrine carcinoma therapeutics was valued at \$126.9 million in 2011, and is expected to grow at a CAGR of 17.9% to \$475.1 million in 2019. The U.S. market will contribute the most to global revenue in the forecast period, followed by Germany and other major markets. The GI carcinoid NETs therapeutics market was dominated by Sandostatin LAR (octreotide acetate), the only approved drug for GI carcinoid NETs. Before the launch of Sutent (sunitinib) and Afinitor (everolimus) in 2011, the pancreatic NET market was dominated by off-label drugs such as 5-FU, doxorubicin, etoposide, decarbazine (DTIC), streptozocin, cisplatin, and cyclophosphamide.

Source: GlobalData, Neuroendocrine Carcinoma Therapeutics — Pipeline Assessment and Market Forecast to 2019

▼ For more information, visit globaldata.com.

The global prostate cancer market was valued at an estimated \$3.8 billion in 2012. GlobalData expects the market to grow to \$7.9 billion by 2022, with more than 50% of sales coming from the United States. With the launch of Johnson & Johnson's Zytiga and Medivation/Astellas' Xtandi, the prostate cancer market is shifting toward domination by targeted therapies. Astellas and J&J are poised to overtake incumbent players as the market leaders following the launch of premium-priced drugs that are orally administered and are well tolerated by patients.

Source: GlobalData, Prostate Cancer — Global Drug Forecast and Market Analysis

▼ For more information, visit globaldata.com.

CARDIOVASCULAR

The global anticoagulant drug market was valued at

about \$5.8 billion in 2011 and should reach \$5.7 billion in 2012. Total market value is expected to reach about \$5.4 billion in 2017 after decreasing at a CAGR of 1.1%. The market in the United States is expected to have a value of \$2.8 billion in 2012 and \$2.2 billion in 2017, a CAGR of (4.5%). Europe should total \$1.6 billion in 2012 and \$1.6 billion in 2017, a CAGR of (0.3%). Japan is expected to total \$504 million in 2012 and reach nearly \$509 million in 2017, a CAGR of 0.2%. The rest of the world is expected to have a value of almost \$703 million in 2012 and reach \$996 million in 2017, a CAGR of 7.2%.

Source: BCC Research, Antithrombotic/Anticoagulant Drugs: Technologies and Global Markets

▼ For more information, visit bccresearch.com.

The combined markets for drugs used in the primary prophylaxis of venous thromboembolism (VTE) as well as acute treatment and secondary prophylaxis of VTE will increase moderately from \$4.1 billion in 2011 to \$5.1 billion in 2021 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. The market shares of low-molecular-weight heparins and vitamin K antagonists continue to be gradually eroded by the uptake of novel oral anticoagulants in Europe for VTE prevention after orthopedic surgery. The near-term launches of oral agents for VTE treatment/secondary prophylaxis will trigger a sharp decline in the fortunes of low-molecular-weight heparins and vitamin K antagonists. In 2011, low-molecular-weight heparins and vitamin K antagonists were the leading therapies for VTE treatment/secondary prophylaxis and primary prophylaxis.

Source: Decision Resources, Pharmacor advisory Venous Thromboembolism

▼ For more information, visit decisionresources.com.

DIABETES

The global market for diabetes therapeutics and diagnostics was valued at \$110 billion in 2011 and should reach almost \$118.7 billion in 2012. Total market value is expected to reach about \$157 billion in 2017 after increasing at a five-year compound annual growth rate (CAGR) of 5.7%. The U.S. is expected to have a value of \$43 billion in 2012 and \$54 billion in 2017, a CAGR of 4.7%. Europe should total \$26.8 billion in 2012 and \$35.4 billion in 2017, a CAGR of 5.7%. Asia is expected to total \$48.9 billion in 2012 and \$67.3 billion in 2017, a CAGR of 6.6%.

Source: BCC Research, Global Markets for Diabetes Therapeutics and Diagnostics

▼ For more information, visit bccresearch.com.

HIV

The HIV/AIDS therapeutics market in the top seven markets was valued at \$13.5 billion in 2011, increasing at a CAGR of 12.5% between 2004 and 2011. The market is projected to witness growth of 7% during the 2011-2018 forecast period to reach \$21.8 billion. The growth is primarily driven by the increase in the use of single dose multi-class combination drugs such as Atripla and Complera. With the recent launch of Stribild (previously known as Quad), the multi-class combination drugs would drive the market.

Source: GBI Research, HIV/AIDS Therapeutics Market to 2018

▼ For more information, visit gbiresearch.com.

RESPIRATORY

The community-acquired bacterial pneumonia antibiotic market will experience modest growth over the next decade, increasing from about \$1 billion in 2011 to more than \$1.2 billion in 2021 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Sales of inpatient CABP antibiotics will grow by 2% annually, reaching more than \$800 million in 2021, while the outpatient CABP segment will grow at an even slower rate and amount to about \$400 million in 2021. Among emerging therapies, Cemptra's solithromycin, a macrolide, is best poised for success over the next 10 years.

Source: Decision Resources, Pharmacor advisory Community-Acquired Bacterial Pneumonia

▼ For more information, visit decisionresources.com.

VACCINES

Quadrivalent influenza vaccines, which contain antigens against two influenza type A and two influenza type B subtypes, will fundamentally change the composition of influenza vaccines, which are currently trivalent (two influenza A and a single influenza B strains). Sanofi, GlaxoSmithKline, and AstraZeneca will introduce quadrivalent influenza vaccines in the United States and/or European marketplace within the next two years. These newer vaccines will usurp the position of existing trivalent vaccines, leading to a quick path to obsolescence for the latter. The market is relatively stable at about \$2.3 billion during the forecast period, because of the inherent nature of the seasonal influenza virus' antigenic drift.

Source: GlobalData, Seasonal Influenza Vaccines — Global Drug Forecast and Market Analysis Event-Driven Update

▼ For more information, visit globaldata.com.

WOMEN'S HEALTH

The worldwide women's health therapeutics market is forecast to be worth \$22.7 billion by end of 2018, a 2.7% CAGR between 2011 and 2018, driven by the launch of novel molecules such as Elagolix and Odanacatib in the late-stage pipeline, according to GBI Research. But the patent expiries of such blockbusters as Evista, the Premarin family, Forteo, Mirena, among others, will hinder the sector growth.

▼ For more information, visit gbiresearch.com.

drugs accounting for about 70% of the prescriptions dispensed in the United States. This percentage is likely to increase as novel branded drugs face further competition from generic products. Other countries will experience similar trends, the report finds.

Dr. Syed Ahmed, a senior pharmaceutical industry analyst at visiongain, says: "A number of factors have contributed to the growth of the world generics market. Prominent blockbuster drugs will lose patent protection in the next few years, with many having done so already. Novel pharmaceutical manufacturers are set to lose over \$50 billion in sales due to patent expiry in 2013 alone. That situation presents great opportunities for generics producers over the next 10 years. Also, growth in the generics industry and market will continue steadily as legislative demands to control healthcare costs increase, especially in the U.S. and European markets. Many healthcare payers demand generic substitutes for branded prescription medicines, especially drugs with wide use.

▼ For more information, visit visiongain.com.

Regulatory Affairs

BUDGETS RISE

A new study finds that despite budget cuts in pharmaceutical companies as a result of the recession, regulatory affairs teams have experienced a consistent increase in their budgets since 2006. These increases come in the face of continued economic hardship throughout the industry.

The growing prominence of regulatory affairs teams is demonstrated by the budget numbers presented in Cutting Edge Information's study, "Regulatory Affairs: Safeguarding Submission Success and Product Development Strategy," which shows that spending on regulatory affairs groups increased among all sizes of pharmaceutical companies. The most significant percentage increases took place in the smaller companies where budgets increased by nearly 50%. Top 20 pharma companies' regulatory affairs teams experienced average budget growth upwards of \$5 million, which is a significant increase for any department.

▼ For more information, visit cuttingedgeinfo.com.

Bioinformatics Market

PREDICTED TO GROW

The global bioinformatics market is estimated to reach \$9.1 billion in 2018, a CAGR of 25.4% from 2012 to 2018, according to Transparency Market Research. The market growth is driven by a rise in

SALES OF DRUG-DEVICE COMBINATION PRODUCTS (\$ IN MILLIONS)

| Market Segment | 2011 | 2012 | 2017 | CAGR% 2012-2017 |
|--|------|------|------|--------------------|
| Antimicrobial catheters | 6.5 | 6.6 | 11.7 | 12.1 |
| Coronary stents (DES and bioabsorbable) | 5.7 | 5.8 | 8.2 | 7.2 |
| Orthopedic applications (cements and bone substitutes) | 2.7 | 2.8 | 4.1 | 7.9 |
| Photodynamic therapies | 1.6 | 1.7 | 2.6 | 8.9 |
| Orthopedic applications (cements and bone substitutes) | 2.0 | 2.1 | 3.9 | 13.2 |
| Total | 18.5 | 19.0 | 30.5 | 9.9 |

Source: BCC Research

applications across various industries. The key contribution to the market demand is from fields such as agriculture biotechnology, pharmaceutical research and development, medical and clinical diagnostics, and other life-sciences related industries.

The bioinformatics platform holds the largest market share and is estimated to account for almost 50% of the market revenue. The services market currently holds a relatively smaller market share, however, it is expected to increase considerably over the forecast period. The bioinformatics platform segment is the fastest growing market and is expected to contribute 54% of the total market growth during the same period.

▼ For more information, visit transparencymarketresearch.com.

MSL Spending Highest in TOP MARKETS

The highest spending on medical science liaisons (MSLs) occurs in the top markets, with \$11.6 million spent on MSLs in the United States, according to a new study published by Cutting Edge Information.

The study, Managing Medical Science Liaison Teams: Budget, Staffing and Compensation Benchmarks, shows that the MSL budget in the United States is far ahead of the next highest budget in Japan at roughly \$3.2 million. Total budgets for MSLs in countries outside the United States ranged from \$110,000 to \$3.2 million in most markets. But new and upcoming regulations in Germany and the United Kingdom are likely to cause a decrease in MSL budgets in these two markets, currently at \$2.7 million and \$1.9 million, respectively.

In recent years, pharmaceutical companies have been shifting spending on MSLs to emerging markets. Larger field-based teams will more quickly develop these territories, especially where companies have already established commercial or clinical operations. This shift in resources will

help develop growth in these emerging markets, especially in India, Russia, and South Korea, where less than \$200,000 is dedicated to MSL spending.

▼ For more information, visit cuttingedgeinfo.com.

Combination Products to EXPERIENCE GROWTH

The market for global drug-device combination products was valued at \$18.5 billion in 2011 and should reach \$19 billion in 2012. Total market value is expected to reach \$30.5 billion in 2017 after increasing at a five-year compound annual growth rate (CAGR) of 9.9%.


An estimated 30% of all new healthcare products under development are combination products involving medical devices embedded with pharmaceutical or biologics components. The classic example of a combination product that revolutionized patient care is the drug-eluting coronary stent.

▼ For more information, visit bccresearch.com.

M&A in BIOTECH DECLINES

Merger and acquisition activity in the biotechnology sector of the healthcare industry gradually declined in terms of the number of deals announced from January 2009 through 2011, according to a recent study by Irving Levin Associates. The year 2012 looks to be on track to equal the number of deals in 2011.

Dollar volume of transactions peaked in 2010, nearing \$61 billion spent on biotech deals, a 30% increase in total dollars spent over 2009, even though the number of deals actually dropped 33%.

▼ For more information, visit levinassociates.com. 

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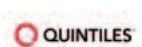
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