



By Carolyn Gretton

▶ Healthcare to Experience

Extreme Makeover in 2011

TREND: Health organizations are expected to undergo another strategic shift in 2011 as they react to new rules and payment models, continuing cost pressures, and new customer demands, as well as the continued evolution of health information technology.

Pharmaceutical companies will see an opportunity to increase their visibility with consumers, influence health outcomes, and reduce healthcare costs while increasing revenue using digital strategies and technology, according to Top Health Industry Issues of 2011, a report published by the PricewaterhouseCoopers (PwC) Health Research Institute. In addition, the use of mobile health and wireless technologies by all health organizations is expected to continue to surge in the coming year.

“Health organizations are placing their bets on the future direction of healthcare and making decisions that will position their businesses for competitive advantage,” says Daniel Garrett, principal, PwC’s health industries technology (HIT) practice. “Some organizations will undergo an extreme makeover, while others will stay the course or refine existing strategies. Whichever path they take, all health organizations will be under pressure to deliver greater value for less, and they will face new risks and realities as business models and market players emerge.”

In the report, PwC also predicts that record spending on health information technology in 2011 will likely increase demand for skilled HIT professionals, an expanded role for chief information officers, and increased merger and acquisition activity among organizations looking to share the cost and benefits of HIT integration.

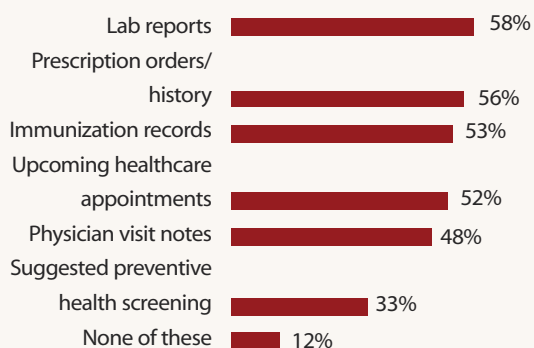
As part of its research for the Top Health Industry Issues of 2011, PwC surveyed consumers about their point of view on reform-related issues. According to the survey, 86% of consumers do not access their medical records electronically, despite vast investments in electronic health records (EHRs) and high hopes that consumers will use EHRs to participate in shared medical decision-making.

▶ For more information, visit pwc.com.



Daniel Garrett

CONSUMERS' ELECTRONIC ACCESS TO HEALTH INFORMATION



Source: PricewaterhouseCoopers, HRI Consumer Survey, 2010.

Emerging Technologies

CONTINUE TO RESHAPE HEALTHCARE

A new wave of technologies is expected to reshape the delivery of healthcare, helping to control costs while improving health by ushering in an era of wellness, self-monitoring, increased and earlier detection of disease, and more effective treatments.

In its recent report, *The Future of Healthcare: It's Health, Then Care*, CSC's Leading Edge Forum iden-

FIVE TECHNOLOGY TRENDS IN HEALTHCARE

- » E-Power to the Patient. Patients will be in charge of their care management on a daily basis, marked by “shared care” between patient and provider.
- » Earlier Detection. Accelerating early diagnoses is crucial to starting treatment for, and preventing, illnesses. Detection options will range from simple, inexpensive technology tests to complex genetic testing.
- » High-Tech Healing. Next-generation implants and ingestible devices will monitor disease progress, dispense medications, and assist and replace malfunctioning organs and limbs.
- » Resources: More, but Different. Care provider roles will change and resources will be more widely available through remote technologies and online communities, for care and consultation as well as teaching and training.
- » Global Healthcare Ecosystem Emerges. A rich ecosystem, armed with data and knowledge, will support more connected care and research collaboration to advance disease identification and treatment.

Source: CSC Leading Edge Forum, *The Future of Healthcare: It's Health, Then Care*.

tifies a wide range of game-changing healthcare technologies in development, such as intelligent pills that deliver targeted doses of medication to specific locations in the body, brain implants that prevent seizures, contact lenses with microchips to detect glaucoma, and bioprinting that creates new skin.

In addition to these high-tech healing tools, the report predicts wireless technology and social networking tools will empower patients to take charge of their healthcare management as a result of the availability of health information, new intelligent health and care applications, and a support system that encourages and monitors progress.

"Healthcare needs significant, disruptive change to address its problems, and there are many maturing technologies that can help," observes Fran Turisco, an emerging practices research principal in CSC's global healthcare services group and the study's lead researcher. "What we have seen to date is only the tip of the iceberg of a wide range of technologies coming out of commercial, government, and university research labs that can make a significant difference for wellness and care delivery."

▼ For more information, visit csc.com.

Pricing Regulation Likely to Increase

ACROSS GLOBAL PHARMA MARKETS

While governments in most of the world's developed economies already regulate the prices of most prescription drugs, their control over prices is expected to tighten in the future, with even some of the countries that traditionally play a limited role in price-setting poised to introduce stricter controls on pharmaceutical pricing.

The recent Decision Resources report, *Pharmaceutical Pricing and Reimbursement: Key Facts in Mature and Emerging Markets*, observes that the German and United Kingdom governments, which have generally allowed manufacturers relative freedom to set the prices of new drugs, plan to introduce value-based pricing. And while the United States will continue to allow free pricing of pharmaceuticals, healthcare reform legislation will increase Medicaid rebates and require manufacturers to offer a 50% discount on drugs prescribed in the Medicare coverage gap.

"Increased pricing control efforts are not limited to mature markets; governments in emerging markets will also intensify their efforts," says Neil Grubert, director of pricing and reimbursement re-



Neil Grubert

search at Decision Resources. "Governments in emerging markets will pay close attention to how proposed prices in their countries compare with prices in other major markets and may demand that manufacturers offer them prices that are lower than those in advanced economies."

▼ For more information, visit decisionresources.com.

PR Can Strengthen Brand

AWARENESS IN EARLY LAUNCH STAGE

The reach and potential of public relations (PR) in generating brand awareness and reaching consumers has greatly expanded through technologies such as websites, online social networks, information alerts, and blogs.

According to the recent Best Practices report, *Public Relations Excellence: Using PR to Launch, Grow and Extend Your Brands*, savvy biopharma marketers have learned to use PR tools such as online communities and information alerts to maintain brand growth and consumer relationships in a

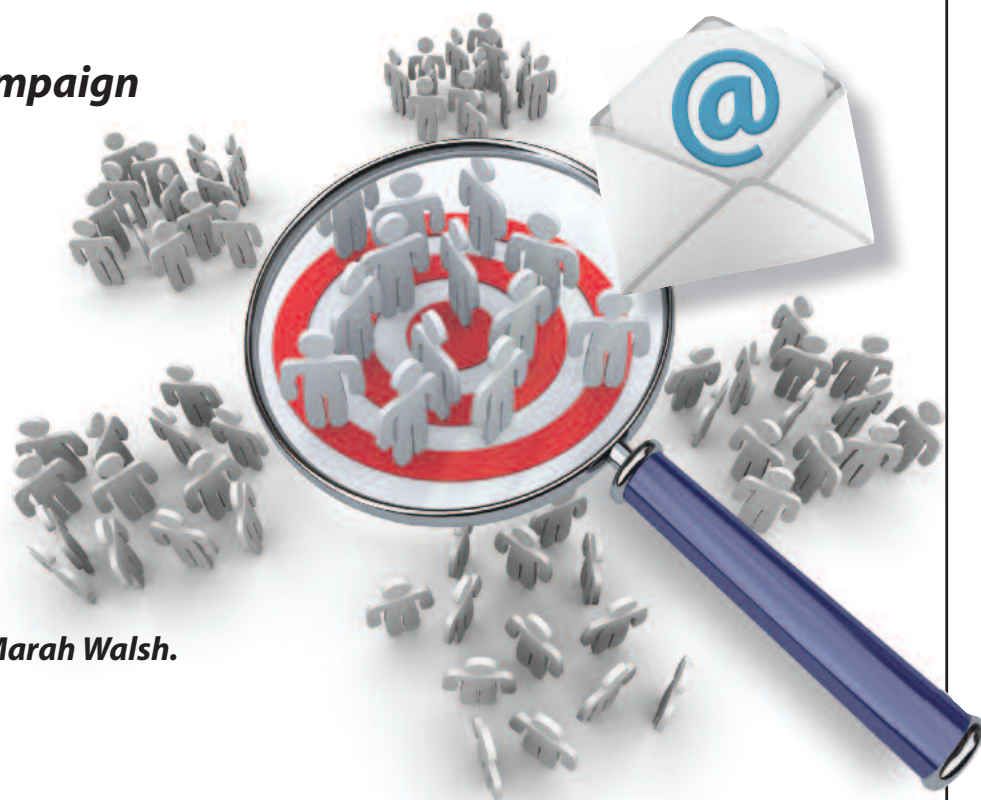
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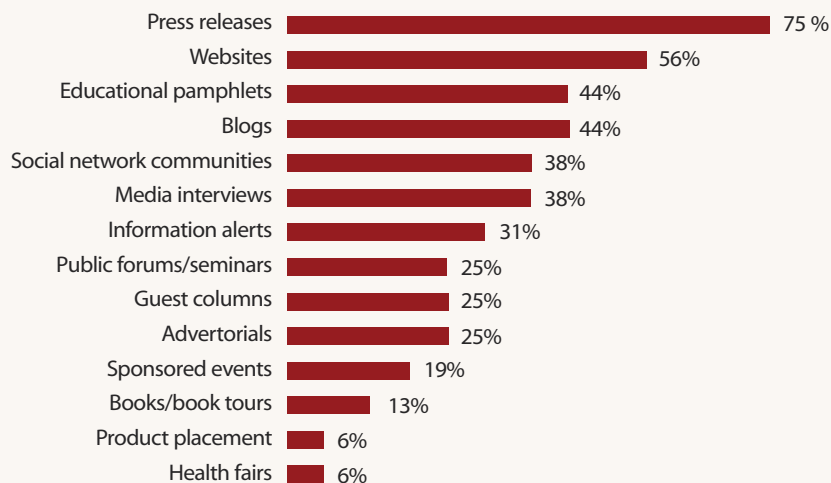
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MOST EFFECTIVE PR PRELAUNCH TOOLS



Source: Best Practices, Public Relations Excellence: Using PR to Launch, Grow and Extend Your Brand.

product's later life, but survey results show that third-party support, such as patient advocacy websites, is most effective during the product's preparation for market entry.

Public relations tools benefit all phases of the product lifecycle. But research participants identify the pre-launch, launch, and growth phases as the highest-impact lifecycle stages for PR influence and effectiveness. Nearly 50% of companies reported public relations effectiveness during product maturity, and 16% reported public relations tools to be effective during product decline.

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

Almost Half of U.S. Adults SEEK PHARMA INFO ONLINE

The ePharma consumer population continues to grow, boosted in part by the increase in the number of older consumers using the Internet in recent years. According to Manhattan Research, in 2010, 112 million or 48% of U.S. adults were ePharma consumers, or individuals online for pharma information, up from 55 million consumers in 2005.

Version 10.0 of Manhattan Research's ePharma Consumer study includes a focus on two key pharma issues for 2011 — treatment adherence and drug spending and assistance — and offers metrics for hundreds of pharma product websites. The study found that most consumers online for pharma information take health-related action after their online research, and they are more likely to discuss the information with their doctor rather than to make treatment decisions on their own.

General health websites are the top online pharma resources in terms of reach and influence, but the research also shows that pharma websites are critical secondary resources that play an im-

portant role during the prescription drug research continuum. Consumers are considerably more

BRAND WEBSITE VISITS

Q: For which of the following reasons did you visit this product website for information for yourself?

I am currently taking this product or take it as needed	33%
I was just seeking additional information	30%
I was interested in seeking information about side effects	17%
I have taken this product previously, but am not currently	15%
I am taking a different product for the same condition	13%
I have the condition, but am not taking a prescription drug for it	12%
My doctor gave me a prescription for this product, but I have not filled it	8%

Source: Manhattan Research, ePharma Consumer v10.0.

likely to use pharma product and corporate websites for prescription drug information than government websites, pharmacy websites, patient association websites, and social media sources.

"Product websites are still valued destinations

despite the dominance of general health websites," says Monique Levy, VP of research at Manhattan Research. "More ePharma consumers use them for pharmaceutical information than social media sources, for example, and their visitors



Monique Levy

represent an action-oriented, high-value group."

▼ For more information, visit manhattanresearch.com.

Role of Medical Affairs

EXPANDS WHILE FUNDING HOLDS STEADY

Over the past several years, the medical affairs organization has evolved into a global group as it has separated itself from marketing. As a result, medical affairs budgets are expected to remain steady or increase slightly in 2011 as life-sciences companies continue to expand the function's global role.

In its recent study, Medical Affairs: Effective Global Resource Allocation, Cutting Edge Information notes that average medical affairs organizational budgets and staffing levels largely remained unchanged from 2008 to 2010 but many observers expect accelerating investment in the near future.

"While it's always been pivotal, the function is slowly taking on greater responsibilities in new and

different areas, including R&D, compliance, and health economics," says Jason Richardson, president of Cutting Edge Information. "Companies support such growth and build elite medical affairs programs by maintaining or increasing



Jason Richardson

resource levels."

A major driver of this steady resource support is a strong focus on relationships with thought leaders and key opinion leaders (KOLs), according to survey data from more than 30 of the largest life science companies. Among sub-teams, medical science liaisons (MSLs) remain the largest single group (30% of medical affairs personnel in 2010, compared with 32% in 2008) and receive the largest budget slice.

▼ For more information, visit cuttingedgeinfo.com. PV



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THERAPEUTIC MARKET FAST TRAX... **BIOTECHNOLOGY**

The total market for nanobiotechnology products is projected at \$19.3 billion for 2010 and is expected to grow at a compound annual growth rate (CAGR) of 9% to reach \$29.7 billion by 2015. Medical applications, including drug delivery and microbicides, dominate today's market, with sales of \$19.1 billion in 2010 expected to increase at a projected CAGR of 8.7% to \$29 billion by 2015.

Source: BCC Research, Nanobiotechnology: Applications and Global Markets.

▼ For more information, visit bccresearch.com.

CANCER

Commercial executives in the oncology therapeutic area make clinical and compound data disclosures earlier than other therapeutic areas. About 40% of surveyed commercial oncology leaders said they communicate mechanism-of-action (MOA) data at the preclinical stage, whereas only 29% of total participants surveyed said they communicate MOA at that time.

Source: Best Practices, Shaping the Marketplace to Support Successful Oncology Product Launches: Tactics for Educating KOLs, Physicians, Patients and Payers.

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

The multiple myeloma drug market is expected to grow 7.2% annually through 2019 amid continued uptake of Celgene's Revlimid in the first-line setting and the launch of several premium-priced emerging therapies. Although the first-line setting is currently dominated by Takeda/Janssen-Cilag/Janssen's Velcade in terms of patient and market share, sales of Velcade are likely to be rapidly eclipsed by the dramatic growth of Revlimid.

Source: Decision Resources, Pharmacor 2010 findings on Multiple Myeloma.

▼ For more information, visit decisionresources.com.

Drug treatment opportunities for advanced colorectal cancer will likely continue to be limited because of a sustained decrease in the recurrence risk in early stages of the disease. Growth in drug treatment opportunities for advanced disease will be limited to 15% between 2009 and 2024, while growth in drug treatment opportunities for newly diagnosed cases is projected at 27%.

Source: Decision Resources, Pharmacor Patient Flow Model, Colorectal Cancer.

▼ For more information, visit decisionresources.com.

Projected improvements in recurrence-free survival and an only modest increase in risk due to population aging will limit growth of new first-line

drug-treatment opportunities for advanced ovarian cancer to 16% from 2009 to 2024.

Source: Decision Resources, Pharmacor Patient Flow Model, Ovarian Cancer.

▼ For more information, visit decisionresources.com.

The biotechnology industry is having a measurable impact on developing new oncology therapies. FDA-approved oncology compounds all heavily used at least one (and some as many as four) special U.S. regulatory mechanisms — such as fast-track designation, orphan-drug status, or accelerated approval — to speed clinical development and reduce FDA transit times, and innovative agents such as those targeting receptor tyrosine kinases achieved up to 31% approval success rates.

Source: Deloitte Recap, Innovative Strategies for Oncology Drug Development.

▼ For more information, visit deloitte.com/us.

CENTRAL NERVOUS SYSTEM

The attention-deficit/hyperactivity disorder (ADHD) drug market in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan is expected to fluctuate modestly over the next decade, decreasing from \$5 billion in 2009 to \$4.1 billion in 2019. An expanding drug-treated population and increasing use of new therapies through 2019 will be unable to fully counter the losses caused by the generic erosion of Shire's Adderall XR and McNeil Pediatrics/Janssen-Cilag's Concerta/Concerta XL.

Source: Decision Resources, Pharmacor findings on Attention-Deficit/Hyperactivity Disorder.

▼ For more information, visit decisionresources.com.

DIABETES

Marketing strategies that engage influential scientific and medical thought leaders in a particular therapeutic area are critical to launching a successful product in today's crowded diabetes marketplace. While companies signaled Phase II as the kickoff point for most of their thought leader engagement efforts and services, some companies with strong pipelines and a longstanding commitment to diabetes are initiating their thought leader services as early as the preclinical research phase.

Source: Best Practices, Educating the Marketplace to Support Successful Diabetes Product Launches.

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

About 60% of surveyed Type 2 diabetes patients in the United States who currently use insulin indicate they would request that their doctor switch them to a less-expensive biosimilar insulin if such an agent became available. Although most surveyed Type 2 diabetes patients indicate that they

have some form of prescription coverage associated with their insurance, patients taking insulin report that they feel their disease is a greater financial burden compared with other patient segments. The majority of surveyed insulin users indicate they are also taking at least one oral antidiabetic agent, resulting in multiple copayments each month and increasing the monthly out-of-pocket cost for these patients.

Source: Decision Resources, Patient Forum report, Patient Forum in Type 2 Diabetes: Patients' resistance to injectable agents may cause challenges for emerging GLP-1 analogues.

▼ For more information, visit decisionresources.com.

DIAGNOSTICS

The market for point-of-care (POC) tests has almost doubled in size from 2003 to 2009, with the market for combined OTC and professional applications of POC testing valued at \$13.3 billion worldwide in 2009. The growth in POC sales, which is projected to continue at 6% annually through 2014, is largely related to significant increases in glucose self-testing of diabetics and to various professional test segments, including critical care and cardiac markers.

Source: Kalorama Information, Worldwide Point of Care Diagnostic Test Markets.

▼ For more information, visit kaloramainformation.com.

Device innovations, demographics, and hospital austerity are expected to drive the global medical device market to \$312 billion in 2011, from \$290 billion in 2009. Growth has been slow the past few years, given the world recession; but as the economy recovers and new middle class customers in emerging markets demand better healthcare services, the pace of revenue growth is expected to be roughly 4% to 6% over the next few years.

Source: Kalorama Information, The Global Market for Medical Devices.

▼ For more information, visit kaloramainformation.com.

GASTROINTESTINAL

Due to superb efficacy, acceptable safety profile, and anticipated launch in all major markets, Ironwood/Forest/Almirall/Astellas's linaclotide is projected to emerge as the market leader for the treatment of irritable bowel syndrome (IBS), garnering blockbuster sales of \$1.1 billion in 2019 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. The overall IBS drug market is forecast to expand at a 14% annual rate from 2009 to 2019.

Source: Decision Resources, Pharmacor findings on Irritable Bowel Syndrome.

▼ For more information, visit decisionresources.com.

THERAPEUTIC MARKET FAST TRAX... **GOUT**

Although Allopurinol remains the gold standard uric acid lowering therapy for gout in the European Union, Teijin Pharma/Ipsen/Menarini's Ade-nuric — currently available in France, Germany and the United Kingdom — has already achieved significant market penetration. The uptake of Ade-nuric is particularly robust in France, where its patient share is about one-half that of Allopurinol in moderate gout patients and is almost equal to that of Allopurinol in severe patients.

Source: BioTrends Research Group, TreatmentTrends: European Gout Study.

▼ For more information, visit bio-trends.com.

By 2019, the acute gout drug market is forecast to triple in size to \$117 million, and the chronic gout drug market will reach \$1.83 billion, with both markets driven by new, high-priced biologic therapies.

Source: Decision Resources, Spectrum Series, Acute and Chronic Gout – New Agents Target Refractory Patients and Tap Market Opportunity.

▼ For more information, visit decisionresources.com.

INFECTIOUS DISEASE

Generic erosion of nine branded agents, including daptomycin (Cubist/Novartis's Cubicin) and levofloxacin (Johnson & Johnson's Levaquin, Sanofi-Aventis' Tavanic, Daiichi Sankyo's Cravit) will significantly constrain growth in the hospital-acquired infections drug market through 2019 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Combined sales of these nine agents are expected to account for 40% of the overall hospital-acquired infections market in 2019, compared with 65% of sales in 2009.

Source: Decision Resources, Pharmacor findings on Hospital-Acquired Infections.

▼ For more information, visit decisionresources.com.

HIV drug development is being driven by increasing numbers of people being prescribed anti-HIV drugs and their changing drug needs over time. HCV is the next most active area of antiviral development after HIV, driven by the need for more affordable, safer, and more effective therapies. Analysts are predicting a fast rate of market growth when two novel, late-stage protease inhibitors receive regulatory approval, which is expected to happen in 2011.

Source: Insight Pharma Reports' The Antiviral Pipeline: HIV, HCV, and Influenza.

▼ For more information, visit insightpharmareports.com.

LUPUS

The unmet need in moderate-to-severe systemic lupus erythematosus (SLE) remains high despite

the recent increased, off-label usage of unapproved immunosuppressant agents such as Roche/Galencia's CellCept and Genentech/Biogen Idec's Rituxan. Only one-third of surveyed rheumatologists feel their moderate-to-severe SLE patients are optimally managed with respect to controlling the signs and symptoms of active disease. Though currently available agents are effective, the toxicity and side effect profiles of these agents effectively limit the ability of patients to stay on immunosuppressive therapy long-term.

Source: BioTrends Research Group, ChartTrends: Systemic Lupus Erythematosus.

▼ For more information, visit bio-trends.com.

MANAGED CARE

Managed care pull-through programs can be highly effective at driving results. In rating four types of pull-through programs, 45% of participants gave the top rating of high impact to general pull-through support programs (aimed at increasing provider awareness of products), while 24% rated therapeutic intervention programs and 23% rated education support programs high impact. By contrast, only 4% found adherence/persistence programs to have a high impact.

Source: Best Practices, Developing Managed Care Pull-Through Excellence.

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

MULTIPLE SCLEROSIS

On most metrics, perceptions of Acorda's Ampyra, the first FDA-approved product for the management of a multiple sclerosis (MS) symptom, have remained consistent or improved since earlier launch waves. More than three-quarters of surveyed neurologists currently prescribe Ampyra, and projected market share increases for the brand are expected to come from both an expanded user base as well as increased use among current prescribers.

Source: BioTrends Research Group, Launch Trends: Ampyra.

▼ For more information, visit bio-trends.com.

With the recent introduction of Novartis' Gilenya, the first oral disease-modifying agent for the treatment of multiple sclerosis (MS), neurologists anticipate major shifts in the landscape of the MS market. Trial and uptake of Extavia, an injectable disease-modifying agent launched by Novartis in 2009, continues to be tempered due to the perception that Extavia is a me-too agent, a perception made even more noticeable by the availability of Gilenya. In fact, compared with previous waves, both current and anticipated patient share of Extavia have decreased due in part to a drop in the number of high prescribers of Extavia.

Source: BioTrends Research Group, LaunchTrends: Extavia.

▼ For more information, visit bio-trends.com.

The majority of surveyed neurologists in the EU5 — France, Germany, Italy, Spain, and the United Kingdom — expect that both Novartis/Mitsubishi Tanabe's oral agent Gilenya and Merck Serono's oral cladribine will most likely secure initial European approval for use in relapsing forms of multiple sclerosis (MS). Neurologists expect the first approved use of either drug will be for the treatment relapsing forms of MS who have failed first-line therapy.

Source: Decision Resources, European Physician & Payer Forum report, Multiple Sclerosis in Europe: How Will Clinician Attitudes and Payer Hurdles Determine How Late-Stage Oral Therapies Will Compete with Current Disease-Modifying Drugs?

▼ For more information, visit decisionresources.com.

RESPIRATORY

An average of 55% of surveyed asthma patients in the United States say they are likely or very likely to request a switch to a drug with efficacy that is comparable to their current medication but which is dosed just once a day. The likelihood of requesting this switch increases with worsening disease control, which is likely due to the fact that somewhat controlled and poorly controlled patients currently use a greater number of drugs and report a greater disease burden.

Source: Decision Resources, Patient Forum report, Patients' Comfort and Familiarity with Current Asthma Treatments May Present Challenges for Emerging Brands.

▼ For more information, visit decisionresources.com.

RHEUMATOID ARTHRITIS

Newer biologic agents such as UCB's Cimzia and Centocor Ortho Biotech's Simponi, although lagging in overall rheumatoid arthritis (RA) market share, have begun to penetrate the first-line biologic position primarily at the expense of Pfizer/Amgen's Enbrel and Abbott's Humira. A comparison of RA patients who were switched to a second-line agent within the past two years found there was an increase in the percentage of patients switching to an alternative mechanism compared with previous years.

Source: BioTrends Research Group, ChartTrends: Biologics in Rheumatoid Arthritis.

▼ For more information, visit bio-trends.com.

Amgen/Pfizer's Enbrel is the leading tumor necrosis factor (TNF)-alpha inhibitor prescribed in newly diagnosed rheumatoid arthritis (RA) patients, outpacing Abbott's Humira in the first three lines of treatment. An estimated 2% of newly diagnosed RA patients receive Enbrel as a first-line drug within a year of diagnosis, while just over 1% of patients receive Humira.

Source: Decision Resources, Treatment Algorithms in Rheumatoid Arthritis.

▼ For more information, visit decisionresources.com.