

PHARMA TRAX

SALES, MARKETING,
AND R&D TRENDS AFFECTING
THE HEALTHCARE INDUSTRY



Pharma Could Benefit from Earlier Planning of **COUNTER-GENERICS STRATEGIES**

Drug research companies are strengthening their task forces to protect the patents for their products, but planning far enough in advance of patent expiration remains a challenge for many, according to a recent Cutting Edge Information study.

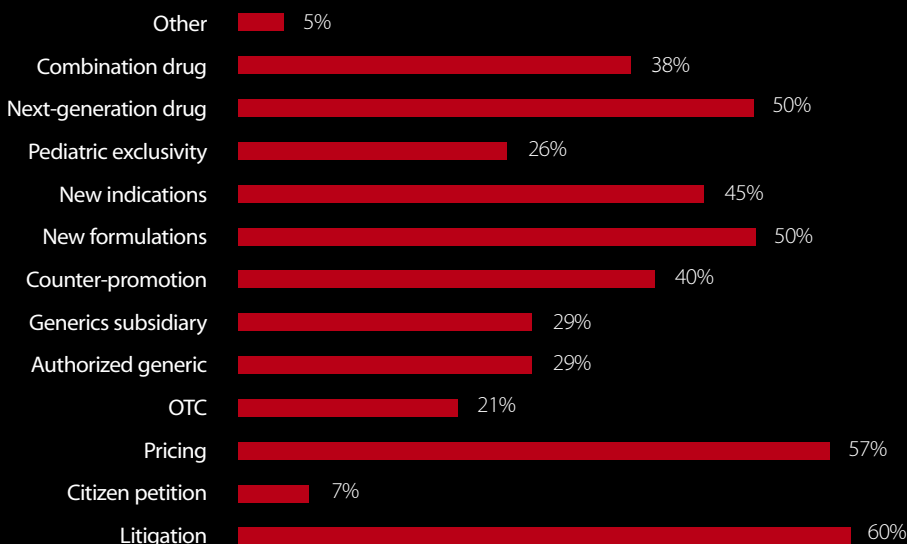
The study, *Countering Generic and Biosimilar*

Threats: Near-Term and Long-Term Strategies, notes that on average, 40% of surveyed companies deploy counter-generics task forces. The study finds that 31% of responding companies form task forces zero to two years from patent expiration, while another 31% form these groups two to four years from patents expiring.

"These groups strengthen cross-functional communication because of the array of functions involved," says Jason Richardson, president of Cutting Edge Information.

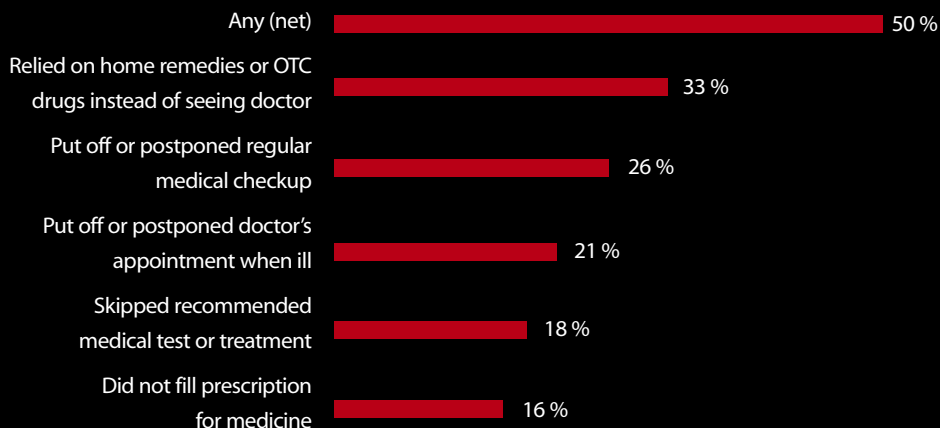
For more information, visit cuttingedgeinfo.com.

COUNTER-GENERICS STRATEGIES USED BY ALL COMPANIES IN PAST 3 YEARS (2008-2010)



Source: Cutting Edge Information, *Countering Generic and Biosimilar Threats: Near-Term and Long-Term Strategies*. For more information, visit cuttingedgeinfo.com.

CHANGES IN MEDICAL TREATMENT IN PAST YEAR DUE TO ECONOMIC CONDITIONS



Source: Pink Tank and Meredith Research Solutions, 2010 *She Says Survey: Will she say yes to your brand?* For more information, visit knowher.com.

More Women Seek **HEALTH INFORMATION**

Recent survey results reveal that women are seeking more information than ever when making their healthcare decisions, but are relying less on their doctors and more on information they gather from multiple sources. According to the *She Says* survey conducted by Pink Tank, a division of global agency GSW World-wide specializing in women and health, in partnership with Meredith Research Solutions, while women still report trust in their doctors, half of women feel empowered to rely on themselves instead.

Gretchen Goffe-Wagner



The point of sale, long considered to start and end with the doctor appointment, is now more fluid, extending before and after the appointment. This could significantly impact how marketers can effectively reach women, says Gretchen Goffe-Wagner.

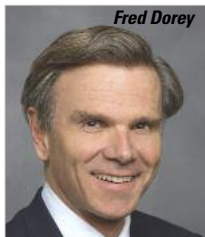
"As they age into high healthcare consumption years, baby boomer women are becoming uber-consumers," observes Gretchen Goffe-Wagner, senior VP, brand planner, for Pink Tank. "The *She Says* survey indicates they are more confident in making healthcare choices for themselves and their families."

As an example, survey data show 40% of women will continue to evaluate a new prescription before deciding if they will fill it after leaving the doctor's office, giving a new significance to the post-script conversation. While some women want to check the cost, most want to learn more about the side effects.

For more information, visit knowher.com.

BIOTECH EXECUTIVES

Show Strong Interest in HCRA Tax Credits



Fred Dorey

We are seeing great interest and excitement about the new tax credit program, and the potential for job creation is clear from this survey, says Fred Dorey.

Almost 90% of biotechnology executives responding to a recent Cooley survey say they intend to complete an application for the Qualifying Therapeutic Discovery tax credit and grant provisions of the Health Care Reform Act, and 40% indicate they plan to submit multiple applications for projects to qualify for the tax credits or grants.

Survey data indicate about 64% of submissions will be for therapeutics projects, followed by device/device-therapeutics (27%) and diagnostics (9%). Respondents forecast that most submissions will be for early-stage projects, with 47% being at the research or preclinical stage. Phase I and Phase II clinical-stage projects make up 34% of anticipated submissions, while later-stage projects comprise 19% of projected submissions.

"We look forward to working closely with clients to ensure their applications are fully compliant and as persuasive as possible," says Fred Dorey, an attorney in Cooley's life sciences practice.

For more information, visit cooley.com.

NOVO NORDISK TAKES TOP SPOT Among Endocrinologists

Novo Nordisk bumped Lilly from the No. 1 spot among endocrinologists in the 12-month period ended April 2010 as the company boosted its call volume to these specialists by 30%, according to SDI's Pharmaceutical Company Image 2010 study.

Study data show that Novo Nordisk was mentioned by 62% of the endocrinologists who participated in the annual study, up significantly from a year earlier, when it was mentioned by 52% of participants and ranked second. Lilly, ranked first by the specialty in the 2009 study, finished second this year even though its percentage of mentions remained relatively stable at 52%, down slightly from 53% a year earlier.

During the 12 months ended April 2010, Lilly representatives made the most sales calls to endocrinologists, accounting for 12% of all calls to this specialty group, followed by Novo Nordisk, which accounted for 10%.

For more information, visit sdihealth.com.

SITE PERCEPTIONS OF CENTRALIZED VS. LOCAL ECG PROVIDERS

Accuracy	35%	60%	5%
ECG clarity	29%	59%	12%
Responsiveness	27%	43%	30%
Cost	26%	44%	30%
Completion time	23%	39%	38%

■ Better/Much Better ■ Same ■ Worse/Much Worse

Source: Tufts Center for the Study of Drug Development (CSDD), Mapping Adoption of Centralized Cardiac Safety Assessment. For more information, visit csdd.tufts.edu.

AUTOMATION OF REMS Programs Essential to Maximizing Patient Benefit

The passage of the Food and Drug Administration Amendments Act of 2007 (FDAAA) mandated enforceable guidelines referred to as Risk Evaluation and Mitigation Strategies (REMS). Designed and implemented properly, a REMS program both protects patients from known or potential serious risks, and offers an economic upside to the biopharmaceutical business.

iReminder's Risk Mitigation Regulation and Compliance Review recommends a number of REMS best practices based on several case studies of systems built to meet the most rigorous REMS requirement, called Elements to Assure Safe Use (ETASU).

"Based on this extensive review, we were able to assemble a list of best practices and recommendations for designing REMS ETASU programs," says Jean Steckler, senior VP of iReminder.

Some of the best practices recommended in the iReminder report include replacing paper-based communications between HCPs, pharmacists, and patients with online systems to improve efficiencies and reduce administrative work and automating various elements of compliance programs through incorporation of IVR, e-mail, and SMS text reminders to patients, as well as alerts to HCPs and pharmacists regarding patient noncompliance.

For more information, visit ireminder.com.

Pharma Companies Recognize Benefits of CENTRALIZED CARDIAC SAFETY MONITORING

According to a recent study conducted by the

Tufts Center for the Study of Drug Development (CSDD), a significant increase in centralization of cardiac safety assessments is anticipated over the next five years, with regulatory pressures and sponsors' need to provide high-quality data being highlighted as key driving factors.

The study, Mapping Adoption of Centralized Cardiac Safety Assessment, supported by an unrestricted grant from ERT, is focused on the use and adoption of digital and electronic ECGs and reports industry perceptions regarding the use of a centralized cardiac safety assessment provider in support of clinical studies.

Results of the study indicate that respondents feel centralized core labs are a valuable way of conducting cardiac safety assessments.

While only 33% of respondents currently use a centralized ECG approach, 89% of respondents expect the use of centralized ECGs to increase in five years.

The significant increase in centralization is anticipated because of regulatory pressures and sponsors' needs to provide high quality-data.

Most industry executives interviewed believe that 100% of all cardiac safety studies will eventually be handled by centralized providers.

About 97% of respondents rated central labs as being more accurate, and 90% of respondents rated them as being more efficient than a decentralized approach.

"The study highlights the growing adoption of centralization, as our sponsors are realizing the need for and benefits of a core ECG laboratory," ERT CEO Mike McKelvey notes.

For more information, visit csdd.tufts.edu.



Mike McKelvey

With more accurate, higher quality, and standardized data at a lower cost, the positive benefits of centralization are now much better understood by industry professionals, says Mike McKelvey of ERT.

QUICK FACTS

- The global market for antipsychotic drugs was an estimated \$18.7 billion in 2009, but is expected to decrease to \$14.8 billion in 2014, for a 4.6% decrease in the five-year compound annual growth rate (CAGR). The decline is mainly attributable to the typical antipsychotics segment, which is anticipated to plummet from \$1.1 billion in 2009 to only \$258 million in 2014, for a CAGR of -25.6%.

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

- The growing importance of the medical affairs function coincides with a company's need to manage rapidly changing regulatory requirements in today's biopharmaceutical industry. This year, 32% of companies anticipate an increase in medical affairs funding of more than 10%. But a top challenge still on the minds of medical affairs executives is insufficient resources, including budget and headcount, for developing and maintaining an effective medical affairs group.

Source: Best Practices, Medical Affairs Resources, Structures & Trends. For more information, visit best-in-class.com.

- No new therapies have been approved for systemic lupus erythematosus (SLE) in more than 50 years, and numerous products have failed in clinical trials. But rheumatologists expressed a high level of interest in Human Genome Science/GlaxoSmithKline's Benlysta, a first-in-class BlyS-specific inhibitor currently under review by the U.S. FDA for SLE. A majority of surveyed rheumatologists say they intend to prescribe Benlysta in the first year of launch.

Source: BioTrends Research Group, TreatmentTrends: Systemic Lupus Erythematosus (SLE). For more information, visit bio-trends.com.

- G-protein coupled receptors (GPCRs) constitute the class of targets most effectively exploited by the pharmaceutical industry, with about 30% of all currently marketed drugs acting on one or more GPCRs and accounting for revenue of more than \$60 billion in 2009. Still, the vast majority (about 80%) of GPCRs have yet to be effectively or commercially exploited for a variety of reasons, thus offering many opportunities in this category.

Source: Business Insights, The Future of GPCRs in Drug Discovery: Novel Technologies, Leading Companies, and Opportunities for Target Expansion. For more information, visit marketresearch.com.

- Pharmaceutical companies vary in their decision to stay in-house versus outsourcing medical information call centers and in how much to

spend on call center support for brands. The majority of companies participating in the study employ a combination of internal and outsourced medical information call centers. About 30% of companies maintain only internal call centers, whereas 15% report using outsourced facilities only.

Source: Cutting Edge Information, Evolving Medical Information Call Centers. For more information, visit cuttingedgeinfo.com.

- Half of all antiretroviral sales in 2019 will be attributed to current pipeline products, as fixed dose combinations increase in dominance over the next decade. A rising patient population, increasing life expectancy, and improved testing strategies will push up demand for products over the period. But sales of existing products are still expected to shrink by a negative CAGR of 6% because of patent expirations and pressures to reduce healthcare spend following the economic downturn.

Source: Datamonitor, Forecast Insight HIV. For more information, visit datamonitor.com.

- Sales of antiepileptic drugs totaled \$3.5 billion in 2009 across the seven major markets of the United States, Japan, France, Germany, Italy, Spain, and the United Kingdom. The combination of continuing strong historical growth dynamics and the uptake of the late-stage pipeline drugs is expected to result in the market value peaking at \$5.1 billion in 2017, after which a new wave of patent expirations hits the United States.

Source: Datamonitor, Pipeline Insight: Epilepsy. For more information, visit datamonitor.com.

- Melanoma cases are expected to almost double in the seven major markets of the United States, Japan, France, Germany, Italy, Spain, and the United Kingdom before the end of the decade, from an anticipated 138,000 new cases this year to 227,000 new cases in 2019, as a result of continued exposure to risk factors. While no major breakthroughs with cytotoxic agents or cytokines have been made for the last three decades, the next generation of systemic melanoma treatment will consist of compounds that target specific molecular pathways, which may or may not be unique to individual patients.

Source: Datamonitor, Stakeholder Opinions, Melanoma 2010. For more information, visit datamonitor.com.

- About 74% of surveyed dermatologists report they will increase their use of Centocor Ortho Biotech's Stelara over the next year for the treatment of psoriasis. As a result, 44% of these physi-

cians will decrease their use of Amgen/Pfizer/GlaxoSmithKline's Enbrel. Surveyed dermatologists are highly satisfied with Stelara's efficacy and dosing, and perceive it to be No. 3 out of eight surveyed brands, just behind Enbrel and Abbott's Humira.

Source: Decision Resources, Brand Perception Series: Physician Segmentation in Psoriasis. For more information, visit decisionresources.com.

- The non-small-cell lung cancer drug market in Brazil is projected to reach \$240 million by 2014, fueled by a slight but steady annual increase in the number of incident cases, greater uptake of higher-priced brands of chemotherapy, targeted regimens and maintenance treatment in the advanced setting, and modest uptake of novel targeted agents.

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

- The launch and uptake of novel oral anticoagulants and antiarrhythmic agents — specifically, drugs from Boehringer Ingelheim, Bayer/Johnson & Johnson, Bristol-Myers Squibb/Pfizer, and Sanofi-Aventis — is forecast to spur an eight-fold increase in the atrial fibrillation drug market, from \$843 million in 2009 to \$6.8 billion in 2019. In 2019, novel oral anticoagulants are expected to capture nearly three-quarters of the atrial fibrillation drug market in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

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

- Rapid uptake and market penetration of key targeted agents, beginning with Roche/Genentech/Chugai's Herceptin, is forecast to drive the gastric cancer drug market to more than double, from \$700 million in 2009 to almost \$1.5 billion in 2019. The robust acceptance of Herceptin, which gained European approval for the indication earlier this year, marks the beginning of a new era of targeted treatment for gastric cancer.

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

- The uptake of two emerging agents from Forest/AstraZeneca/Takeda and Trius is expected to drive an increase in the methicillin-resistant *Staphylococcus aureus* (MRSA) from \$631 million in 2009 to \$752 million in 2019 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Forest/AstraZeneca/

Takeda's ceftaroline and Trius's torezolid are anticipated to capture more than one-third of the MRSA drug market in 2019.

Source: Decision Resources, Pharmacor 2010 findings on Methicillin-Resistant Staphylococcus Aureus. For more information, visit decisionresources.com.

■ In the multiple sclerosis drug market, Novartis/Mitsubishi Tanabe Pharma's oral disease-modifying therapy Gilenia (fingolimod/FTY-720) remains on track to achieve blockbuster status by 2018, following a recent positive recommendation by a U.S. Food and Drug Administration (FDA) panel regarding Gilenia's safety and efficacy in the treatment of relapsing forms of the disease. Following its expected approval, Gilenia is projected to gain major-market peak-year sales in excess of \$1 billion.

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

■ Through 2019, projected 4.1% annual growth in the renal cell carcinoma drug market will likely be driven primarily by the uptake of Glaxo-SmithKline's angiogenesis inhibitor Votrient/Patorma, the launches of premium-priced emerging therapies, and an increase in diagnosed incidence and treatment rates. Votrient/Patorma is expected to become the market leader and garner sales of roughly \$630 million in 2019 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

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

■ Based on clinical profiles provided to them, surveyed clinicians estimate that one year after the launch of Vertex Pharmaceuticals/Johnson & Johnson/Mitsubishi Tanabe Pharma's telaprevir and Merck's boceprevir, at least 90% of hepatitis C virus (HCV) patients will be treated with triple therapy regimens. Surveyed physicians expect to treat 71% of treatment-naïve and 78% of nonresponder patients with telaprevir/peg-IFN/ribavirin and 19% of treatment-naïve and nonresponders with boceprevir/peg-IFN/ribavirin.

Source: Decision Resources, Physician & Payer Forum report, Hepatitis C: Reimbursement and Uptake of Novel Antivirals Among Payers and Prescribers. For more information, visit decisionresources.com.

■ New avenues are unfolding for companies engaged in leveraging medical technologies to unleash devices that target debilitating neurological disorders. The emerging market is show-

ing signs of promising returns for both entrepreneurs and investors in clinical application areas such as refractory epilepsy, treatment-resistant depression, stroke rehabilitation, incontinence, and retinal degenerative disorders. So far, major market share has been limited to four leading competitors — Medtronic, St. Jude Medical, Boston Scientific, and Cyberonics — but a jump in industrial activities and increase in competition is expected in the next two years, when most of the innovative neurostimulation technologies will be introduced in the global market.

Source: Frost & Sullivan, Technical Insights, Advances in Neurostimulators. For more information, visit frost.com.

■ The global neutropenia market is estimated to grow by 4% annually for the next seven years to reach \$8.6 billion in 2016, primarily as a result of increased uptake of biologics and the presence of strong pipeline candidates. Growth will be supported by increases in incidence and prevalence of the disease and the high prescription rate of the currently marketed products.

Source: GlobalData, Neutropenia - Drug Pipeline Analysis and Market Forecasts to 2016. For more information, visit globaldata.com.

■ The pancreatic cancer market is forecast to exhibit a decrease in CAGR of 4.1% between 2009 and 2016, mainly as a result of the projected patent expiration of Gemzar and Xeloda. Although new products currently in Phase III are likely to enter the market soon, it will take some time for physicians to shift their present pattern of usage from Gemzar to the new products.

Source: GlobalData, Pancreatic Cancer - Drug Pipeline Analysis and Market Forecasts to 2016. For more information, visit globaldata.com.

■ Many companies have recognized the potential benefits of epigenetic-based diagnostic and therapeutic products, with four epigenetic drugs having been approved by the U.S. Food and Drug Administration. Celgene's Vidaza, approved to treat 5 FAB subtypes of myelodysplastic syndromes (MDS), generated an estimated \$387 million in sales in 2009, while Eisai's MDS therapy Dacogen posted U.S. sales of \$150 million.

Source: Insight Pharma Reports, Epigenetic Drug & Diagnostic Pipelines: DNA Methylation, HDAC Inhibitors, and Emerging New Targets. For more information, visit insightpharmareports.com.

■ Russia, Hungary, and Ukraine are among the nations seeing investment from pharmaceutical companies as they reduce costs and find

experts in drug discovery activities. A major trend that continues to gain momentum is the use of outsourcing partners in Eastern Europe, one of several trends that is driving the global drug discovery market to \$7.2 billion in 2009, up 15% from \$6.3 billion in 2008.

Source: Kalorama Information, Outsourcing in Drug Discovery: The Contract Research Organization (CRO) Market, 4th Edition. For more information, visit kaloramainformation.com.

■ The pharmaceutical market may soon see the result of an increase in research and development at big pharma companies over the past few years. The top 50 pharmaceutical companies worldwide have some 550 projects in late-stage development, which have the potential to add more than \$70 billion in additional revenue to the pharmaceutical market by 2015.

Source: Kalorama Information, World Pharmaceutical and Biopharmaceutical Market, 2010-2015 (Pipeline Analysis of the Top 50 Companies). For more information, visit kaloramainformation.com.

■ The patient monitoring market in the BRIC countries of Brazil, Russia, India, and China was valued at an estimated \$383 million in 2009. The patient monitor device segment is the highest contributor, with a market share of 82%, and China is the leading patient monitor market among BRIC nations, with a value of \$182 million in 2009.

Source: MarketsandMarkets, Emerging Markets (Brazil, Russia, India, and China): Patient Monitors 2010-2014. For more information, visit marketsandmarkets.com.

■ The global neurotechnology industry posted a 1.2% decline in revenue to \$143.1 billion in 2009. Revenue from neurodiagnostics declined 11% to \$15 billion, while neurodevices revenue jumped 15% to \$7.1 billion and neuropharmaceuticals revenue remained relatively flat at \$121 billion. Venture capital investment in neurotechnology increased 9.5% to \$1.58 billion for the year.

Source: NeuroInsights, Neurotechnology Industry 2010 Report. For more information, visit neuroinsights.com.

■ About 71% of biopharmaceutical industry professionals say they currently have integrated or are in the process of integrating a number of e-clinical systems toward the goals of improving processes and overall trial data accuracy. A smaller group of respondents (21%) claimed to see the value of integrating their systems, but have not done so to date.

Source: Perceptive Informatics. For more information, visit perceptive.com.