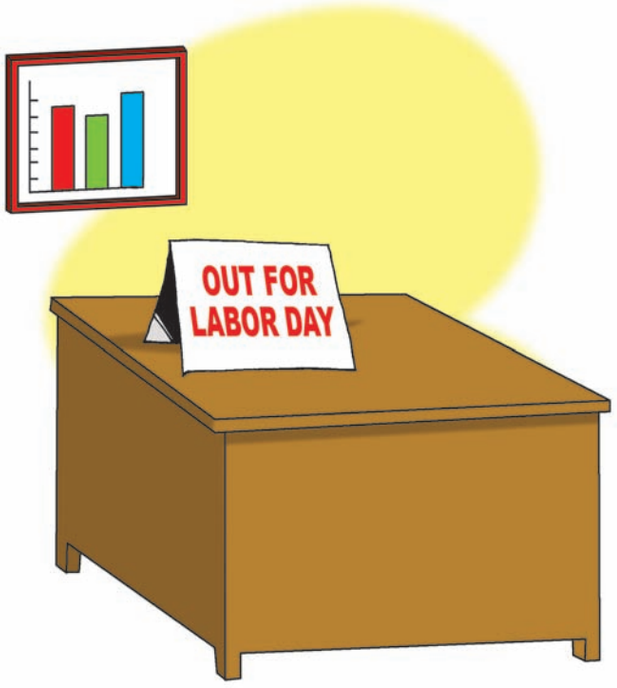

Lipitor **PERCEIVED AS MARKET LEADER** Among Statin Brands


Bradley Silver

Though the statins market continues to be quite lucrative for pharmaceuticals, the general feeling, online, toward these drugs is negative. This is a trend that marketers in the life-sciences industry should be watching very closely, says Bradley Silver, President, BrandIntel.

When it comes to statins, the most frequently discussed issue in the blogosphere and general online world is the negative side effects. This is one of the findings in a recent report fielded by BrandIntel titled, Statins Cholesterol Treatment Competitive Landscape. Another statistic in the report is that Lipitor is perceived to be the market leader in online discussions, with Crestor being the most positively discussed brand.

Through the tracking of more than 131,000 targeted Web pages, BrandIntel found a number of specific trends.

The findings of the BrandIntel's report include:

- Lipitor received the largest share of online discussion, although Lipitor faces criticism from consumers for having strong side effects causing muscle problems;
- Zocor and Crestor closely followed Lipitor in online discussions, with Zocor also facing high volumes of discussion on negative side effects;
- Discussion share for Zocor has continued to rise since second quarter 2006, coinciding with Zocor's patent expiration;
- While it has not generated levels of discussion on par with Lipitor or Zocor, perceptions toward Crestor have been more positive;
- Overall, side effects were the most addressed topic of consumer discussion.

Study Finds **RFID CAN ACCELERATE PIPELINE DEVELOPMENT**

A recent survey of the pharmaceutical industry uncovered attractive opportunities for the use of RFID during discovery, clinical trials, and ramp up to production processes, which currently rely largely on manual data capture. The study, by ChainLink Research, found opportunities for use of RFID during trials for monitoring dispensing of placebo versus active compounds and tracking the correlation of dispensed drugs to patients' outcomes, among other uses. The highest expected use during ramp up production was monitoring the chain of custody, followed closely by monitoring temperature and the state of products.

The study found widespread anticipation among industry participants that more reliable and timely data and access to a single version of data has the potential to considerably reduce time to market. The increasing number of players and steps in these complicated processes — due largely to outsourcing to CROs and contract manufacturers — is creating urgency and concerns about the ability to control and monitor samples from source to clinical environment to production.

Participants were surveyed on which systems are used to capture information for each of the clinical trials processes. The report also covers the challenges and obstacles to using RFID, such as technical and corporate culture issues.

KENDLE RATED TOP CRO by U.S. Investigative Sites in 2007 Survey

Kendle was the highest rated CRO in a 2007 survey of more than 500 U.S. clinical investigative sites. The survey was conducted by Thomson CenterWatch. Kendle led rankings among site investigators in responsiveness to inquiries, knowledge of clinical research associates/managers, and maintaining open communications.

Across the 29 relationship attributes CROs were rated on in the survey, 76% of sites rated the company's performance good or excellent.

NANO'S FUTURE Lies in Healthcare Market

The nanomaterials boom has ended and future growth opportunities in the nanotechnology sector lie in pharmaceutical and healthcare applications, according to a white paper published by Cientifica.


Tim Harper

The window of opportunity for nanomaterials companies is closing fast as global multinationals snap up intellectual property and ramp up production, says Tim Harper, Cientifica CEO.

The report, Half Way to the Trillion-Dollar Market? A Critical Review of the Diffusion of Nanotechnologies, uses an economic model based on primary research that quantifies the impact and diffusion of nanotechnologies, allowing more accurate quantification of market impacts than was previously possible.

The analysis of both public and private spending shows that the number of producers of nanomaterials has decreased as consolidation has increased, and multinational chemical companies now dominate the market. Today, most of the nanomaterials heralded just a few years back as new high-value materials are quickly taking on a bulk commodity stature.

The report reveals that, while this commoditization and consolidation means that little money remains to be made by producing nanomaterials, the ability of these nanomaterials to enable higher-value products will lead to a $1.5 trillion market by 2015.

The report concludes that the market for products enabled by nanotechnologies will reach $263 billion by 2012 and $1.5 trillion by 2015.

After 10 years of research and development, the highly developed supply chain and stability of commercially available nanomaterials is finally enabling higher value-added applications.

The chemical industry will continue to dominate the market until 2012 when bio-related applications will become a larger market. Highest growth rates will be in the healthcare and pharmaceutical sectors, accounting for 80% of the 2015 market. A detailed analysis of the period 2006-2012 shows that the rapid increase in the pharmaceuticals and healthcare market will not begin to take place until 2009-2010, but will surpass the chemical market by mid 2011.

NEUROTECH INDUSTRY REVENUE Up in 2006

Providing market analysis and strategic investment insight into the global neurological disease and psychiatric illness markets, the Neurotechnology Industry 2007 report — Drugs, Devices and Diagnostics for the Brain and Nervous System — reveals revenue in the neurotech industry grew 10% to $120.5 billion in 2006.

The report focuses on the more than 500 public and private companies translating advances in neuroscience into tomorrow's treatments. It provides insight and analysis of issues such as corporate financing, market activity, growth drivers, and global industry conditions that make up the obstacles and opportunities facing the industry. The report looks at 15 brain


Zach Lynch

In the past year we've reached some important milestones, including formation of NIO, the first industry organization devoted to the specific needs of neurotechnology companies, says Zach Lynch, Founder of NeuroInsights and Executive Director of the Neurotechnology Industry Organization.

and central nervous system disorders, including Alzheimer's disease, addiction, anxiety, attention disorders, depression, epilepsy, hearing loss, insomnia, memory decline, obesity, pain, Parkinson's, psychiatric disorders, stroke, and other brain-related illnesses.

"Countless opportunities exist as visionary researchers tackle the complexities of brain-related health and visionary companies, organizations, and policy makers address the complexities of bringing those discoveries to the billions of people suffering from brain-related illnesses," says Zack Lynch, founder of NeuroInsights and executive director of the Neurotechnology Industry Organization.

Specific findings from the 2007 Report include:

- Brain-related illnesses afflict more than 2 billion people worldwide.
- The worldwide economic burden of this problem has reached more than $2 trillion per year; more than $1 trillion in the United States alone.
- 2006 venture capital investment in neurotechnology rose 7.5% to $1.67 billion.
- Neurotech industry revenue rose 10% in 2006 to $120.5 billion; this includes neuropharmaceutical revenue of $101 billion, neurodevice revenue of $4.5 billion, and neurodiagnostic revenue of $15 billion.
- The Neurotech Index of publicly traded neurotechnology companies was up 53% from its Dec. 31, 2003, conception to March 31, 2006, outpacing the NASDAQ Biotech Index, which gained 7% during the same period.

Nation's **LIFE-SCIENCES FIRMS REPORT PROGRESS** with the FDA

The nation's pharmaceutical, biotechnology, and medical-device companies report that the FDA has made progress with improved guidance, expectations, and approvals, but the industry remains concerned about a number of regulatory challenges. A national report outlines a series of issues that still need to be resolved to improve product review delays and shorten the approval process via user fees.

These findings are part of the fourth survey of the medical device and life-sciences industry released by Biocom and PricewaterhouseCoopers. The report, Improving America's Health IV, includes detailed recommendations that the industry and the FDA can implement to ensure improvement in a number of areas.

A minority of companies surveyed indicated


Joseph Panetta

This study is very important because the working relationship between the life-sciences industry and the FDA has a critical bearing on the health of Americans, says Joseph Panetta, President and CEO of Biocom, the association for the Southern California life-sciences community.

that the FDA changed its position during the review of product submissions, allegedly for no discernable scientific reason. While the number was small, this can have a significant impact on a company's development program. Other outcomes were that faster turnaround times were most frequently cited (by 61% of all respondents) as the area in which further FDA improvement is most needed and that FDA staffing shortages and turnover remain the biggest ongoing issue for life-sciences firms.

Six in 10 companies surveyed (61%) agreed or strongly agreed that FDA personnel changes resulted in a break in continuity in at least one of their reviews.

The industry believes that FDA reviewers still cannot keep pace with review queues and more than half of all companies responding indicated that goal timeframes have caused the FDA to reject products simply because reviewers run out of time to resolve issues.

Congress authorized companies to pay user fees to remedy the FDA's chronic shortage of resources and accelerate product approval times. However, one-third of life-sciences firms surveyed (33%), including half of medical-device firms (50%), reported that user fees have not decreased product approval times. This finding could prove significant as Congress debates renewal of the Prescription Drug User Fee Act (PDUFA), which expires during 2007.

At the same time, life-sciences companies do not appear to be taking full advantage of better communication and guidance from the FDA. Nearly two-thirds of medical-device companies surveyed (62%) admitted that they are not incorporating the agency's feedback into their product development progress.

The FDA is providing better guidance and clearer expectations. Almost three-quarters of companies surveyed (73%) indicated that FDA guidance documents have improved their understanding of FDA expectations and improved the quality of submissions, and eight in 10 life-sciences companies agreed the FDA has made significant improvements since the FDAMA was enacted.

An overwhelming majority of biologic (86%) and drug company respondents (87%) agreed that pharmacovigilance, or postmarket surveillance of products, is a key issue facing the industry. While companies expressed a desire to become leaders in pharmacovigilance, they indicated a need for FDA guidance on best practices.

EDC SPENDING AND ADOPTION FORECAST

The table below presents Health Industry Insights' estimate of the current size and expected spending growth of the EDC market for 2006-2011.

U.S. Electronic Data Capture by Segment, 2006-2011 (Dollars in millions)

CAGR (%)	2006	2007	2008	2009	2010	2011	% change 2006-2011
Phase I	$33,772	$44,725	$67,006	$98,255	$120,014	$137,754	32.5%
Phase II	$106,119	$137,563	$169,608	$211,637	$234,155	$252,489	18.9%
Phase III	$162,406	$178,155	$186,899	$198,181	$203,759	$206,619	4.9%
Phase IV and non-IND	$45,570	$50,759	$64,109	$79,290	$90,023	$93,938	15.6%
Total	**$347,866**	**$411,202**	**$487,622**	**$587,362**	**$647,951**	**$690,800**	**14.7%**
Growth (%)	**16.5%**	**18.2%**	**18.6%**	**20.5%**	**10.3%**	**6%**	

Source: Health Industry Insights, 2007. For more information, visit healthindustry-insights.com.

EDC POISED TO DISRUPT Life-Sciences Industry

Health Industry Insights estimates investment in EDC solutions to increase at a 14.7% compound annual growth rate (CAGR) and total more than $3.1 billion for 2006-2011. The report, U.S. Electronic Data Capture 2006 — 2011 Spending Forecast and Analysis, predicts 2007 to be a tipping point as the adoption rate for EDC almost doubles from 24.2% in 2005 to 45.2% in 2007.


Chris Connor

EDC is the most disruptive technology to enter clinical development since the introduction of the personal computer itself, says Chris Connor, senior research analyst at Health Industry Insights. This industry has relied on paper-based processes for decades, and we're not seeing the scalability. Today, we're on the verge of an explosive growth for EDC, and we expect the industry will never be the same.

Adoption of EDC, a software-based solution designed to assist in the collection and management of clinical-trial data, will rise significantly across all stages of clinical trials and the estimate is that by the end of this year almost half (45%) of all new clinical trials will be initiated using EDC.

"EDC enables life-sciences companies to conduct adaptive clinical trials that operate in real-time," says Chris Connor, senior research analyst at Health Industry Insights.

Benefits reported by customers using EDC have been quite dramatic. To the technology's first users, improvements in data management-related activities represented the initial proof of EDC's benefits. For companies that have deployed at least two studies using a consistent EDC vendor the benefits are real. For example, the adoption of EDC can consistently cut the time from last visit to database lock by almost 50%.

Clinical operations users are benefiting from the automation of labor- and time-intensive tasks like site management. For example, using the near-time enrollment reporting capability of EDC, project managers can improve insight and execution against their patient recruitment forecasts.

NUMBER OF PILLS NOT A FACTOR in Daily Adherence to Medication

Poor adherence to medication is a recognized medical problem in the United States, costing an estimated $100 billion a year. According to a study sponsored by Procter & Gamble Pharmaceuticals, there is no correlation between the daily number of pills a patient is prescribed to take and how well a patient will adhere to a dosing regimen. The study looked at patients taking a variety of high-blood pressure medicines, specifically calcium channel blockers (CCBs), and presents supportive evidence that adherence to prescribed medication is influenced by a multitude of factors.

The study specifically examined dosing regimen to evaluate whether there was a relationship between that factor and adherence in patients with a copayment of at least $20.

The one-year, retrospective cohort study analyzed more than 19,000 records of health service reimbursement from U.S. health plans within the Medstat MarketScan database, and looked at the prescription refill rates of different CCBs formulated for different daily dosing regimens (once daily, twice daily, and three times daily dosing). All patients were 18 years of age and older and were patients who visited a physician for high blood pressure.

The percentage of patients persisting on their prescriptions was measured at the end of one year. Persistence at 12 months was defined by looking 12 months, +/- 30 days from index date, and evaluating whether the subject had a refill.

The study found that the range of persistence for the once daily drugs varied widely from 17% to 59%. There was no noticeable difference in drugs intended to be given once daily, twice daily, and three times daily. The twice daily/three times daily one-year persistence rates ranged from 44% to 58%.

Brand Managers NOT SATISFIED WITH CURRENT MARKETING MIX

The recent brand manager study from PharmaKinnex gauged the marketing communications preferences of 21 brand managers, based on both phone and e-mail interviews with a targeted group.

According to the discussions, more than one quarter of the respondents feel their current marketing mix is only performing "reasonably well" or "not well at all," while more than 40% of the respondents say they are doing ""very well" or "extremely well."

Turning the tables a bit, brand managers were also asked how they would like to be marketed to. Here, the PharmaKinnex study reveals a split opinion on what brand managers believe is the best approach to help them learn more about integrated marketing approaches. Web, direct mail, and in-person presentations were the methods selected most often.


Michael White

The study results are interesting in that they, among other things, provide some insight into what brand managers are thinking, and what tactics they believe offer the biggest bang for the buck, says Michael White, PharmaKinnex CEO.

Some 80% of the respondents said an integrated direct marketing program is an important part of promoting a brand, with almost half saying this is extremely important. The results show that three out of four respondents currently employ an integrated direct marketing program in their brand's promotional programs. In addition, aside from face-to-face communication, respondents feel that tele-detailing (with offers of samples and/or literature) and tele-conferencing (promotional or consultant advisory boards) are the most effective marketing tactics to drive a positive return on investment.

Survey Shows SITES OVERWHELMED

The results of a landmark survey by ePharmaSolutions identifies how sites feel about their relationships with pharmaceutical companies, their motivations for conducting clinical research, the technology solutions that have really helped them conduct trials more efficiently, and what they think are the major causes of study delays. The survey was conducted covering 1,100 sites in more than 55 countries in the second quarter of 2007.

In the current technology-driven clinical research environment, study sites are overwhelmed and frustrated with the high number of Websites and passwords they have to remember for each study. More

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than 90% of respondents believe that secure document exchange and single-sign-on portal technology will have the most impact on accelerating study launch and streamlining/simplifying the process, exceeding any other technology solution.

The survey asked sites to give feedback on service providers such as CROs and patient recruitment vendors, and found that 85% of sites feel that patient recruitment vendors do not adequately educate patients about a study or screen them properly before referring them to the site.

Physician Communications About Cancer Clinical Trials ARE PIVOTAL TO PATIENT AWARENESS AND ENROLLMENT

While only 3% to 5% of all adult cancer patients participate in cancer clinical trials, fresh data from the American Society of Clinical Oncology (ASCO) finds that the majority of cancer survivors would have considered enrolling in a clinical trial if their physician had made them aware of the option.

The findings, from a study of attitudes toward cancer clinical trials conducted among cancer survivors by the Coalition of Cancer Cooperative Groups with Northwestern University, underscore that physician communication and attitudes about cancer clinical trials are pivotal to patient awareness and enrollment.

The data show that 65% of cancer patients would have been somewhat or very receptive to enrolling in a cancer clinical trial had they been made aware at the time of their initial diagnosis, and the vast majority, 87%, would have considered participating in a trial if their initial treatment had failed. Further, the findings indicate that of those cancer survivors who did enroll in a clinical trial, 84% were encouraged by their physician to participate, while 83% said their physician also made a determined effort to help them find a suitable trial.

Conversely, 100% of cancer patients who declined to consider enrolling in a clinical trial said they were discouraged by their physician from participating, with the majority indicating that their physician exerted little effort to either educate them on the pros and cons of clinical trial participation (69%) or help them find a suitable trial (67%). In addition, of those patients who tried unsuccessfully to enroll, only 7% said their physician encouraged them to participate and 11% made an effort to help them find a suitable trial.

While the public and cancer patients continue to make use of the Internet and other information resources, the most recent findings show that the physician remains the most relied upon and trusted source for healthcare information. Between 2000 and 2005, reliance on one's personal physician increased from 38% to 51%, while physicians surpassed all other healthcare resources as the most trusted information source. Patients and the public turned to cancer organization Websites, patient education materials, advocacy groups, family members, other healthcare professionals, and the media to a lesser degree.

For cancer survivors, reliance and trust in a personal physician was even stronger, with 73% of survivors indicating that they learned of clinical trials from a physician.

Follow up

AMERICAN SOCIETY OF CLINICAL ONCOLOGY, Alexandria, Va., is a nonprofit organization with overarching goals of improving cancer care and prevention and ensuring that all patients with cancer receive care of the highest quality. For more information, visit asco.org.

BIOCOM, San Diego, focuses on initiatives that position the region's life-sciences industry competitively on the world stage. For more information, visit biocom.org.

BRANDINTEL, Toronto, Canada, translates consumer-created content about brands, products, and services into reliable data that help companies advance the science of decision making. For more information, visit brandintel.com.

CHAINLINK RESEARCH, Cambridge, Mass., is an RFID and supply chain research and consulting organization. For more information, visit chainlinkresearch.com.

CIENTIFICA, London, is a nanotechnology information and consultancy company providing information and research. For more information, visit cientifica.com.

THE COALITION OF CANCER COOPERATIVE GROUPS, Philadelphia, improves the quality of life and survival of cancer patients by increasing participation in cancer clinical trials. For more information, visit cancertrialshelp.org.

EPHARMASOLUTIONS INC., Conshohocken, Pa., provides technology-based clinical solutions that improve the way investigator sites are selected, trained, and activated to commence clinical trials and enroll patients. For more information, visit epharmasolutions.com.

HEALTH INDUSTRY INSIGHTS, Framingham, Mass., provides health and life-sciences industry executives, and the suppliers who serve them, with market research and advisory services. For more information, visit healthindustry-insights.com.

KENDLE, Cincinnati, is a global CRO providing Phase II-IV clinical development services to the biopharmaceutical industry. For more information, visit kendle.com.

THE NEUROTECHNOLOGY INDUSTRY ORGANIZATION (NIO), San Francisco, is a nonprofit trade association that represents a broad spectrum of companies involved in neurotechnology, neuroscience research centers, and brain disease advocacy groups across the United States and around the world. For more information, visit neurotechindustry.org.

PHARMAKINNEX, East Brunswick, N.J., is a pharmaceutical marketing firm that provides cost-effective, brand specific multichannel marketing and sales support to pharmaceutical and biopharmaceutical organizations. For more information, visit pharmakinnex.com.

PRICEWATERHOUSECOOPERS LLC, New York, is a provider of industry-focused services for public and private clients. For more information, visit pwc.com.

PROCTER & GAMBLE PHARMACEUTICALS INC., Cincinnati, a division of The Procter & Gamble Co., is a pharmaceutical company that develops and markets a wide range of prescription products. For more information, visit pg.com.

THOMSON CENTERWATCH, Boston, is a publishing and information services company. For more information, visit centerwatch.com.

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