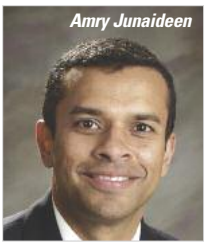
Life-Sciences Companies Unprepared for **INFORMATION SECURITY RISKS**



The life-sciences industry has fallen behind in implementing important foundational technologies, such as identity and access management solutions, partly as a result of inadequate funding of security functions, says Amry Junaideen.

Despite the promise of the information age and the billions of dollars in economic stimulus funding, many life-sciences and healthcare companies have yet to meet lofty expectations of maximizing the value of data and automation efficiencies.

According to Deloitte's 2009 Life Sciences & Health Care Security Study, The Time is Now, inadequate security budgets, the lack of a strong reporting structure, and sophisticated security threats, exacerbated by the stumbling economy, pose significant challenges to information security in the life-sciences sector. Respondents also cited outsourcing data management functions to third-party sources; internal breaches and internal threats, including third party relationships; and protection from data leakage as primary concerns for their information and security programs. Identity and access management were also recognized as top priorities.

"Organizations have the challenge of how to protect their information while facing increasingly sophisticated security threats and increasing regulatory and legislative requirements, all against a backdrop of reduced spending, staff cuts, and organizational changes," says Amry Junaideen, health sciences and government leader, security and privacy, for Deloitte.

For more information, visit deloitte.com/us.

KEY FINDINGS OF INFORMATION SECURITY STUDY

- Data leakage protection is a primary threat-based initiative.
- With the ever-increasing focus on privacy, identity and access management are top priorities.
- The trend toward outsourcing raises a host of third-party security concerns.
- As the business and regulatory environment of the industry evolves, the role of the chief information security officer (CISO) takes on greater significance.
- As the security environment becomes more complex and regulation continues to increase, security budgets fail to keep pace.

Source: Deloitte, The time is Now: 2009 Life Sciences & Health Care Security Study. For more information, visit deloitte.com/us.

Evidence-Based Marketing Critical for **DIAGNOSTIC COMPANIES**

A company investing in evidence-based medicine that demonstrates the cost-effectiveness of a test could go far to ensure future expansion, says Shara Rosen.

With the average cost to develop a new diagnostic test running between $100 million and $200 million, according to a recent Kalorama Information study, in-vitro diagnostics (IVD) companies have little choice but to improve the efficiency of their R&D and commercialization processes.

According to the report, What is Working in IVD: Successful Commercialization of New Products and Technologies, evidence-based medicine is becoming more critical for product success as advances in medical technology create increasingly sophisticated and thus more costly new tests.

"Companies might be tempted to reduce spending on marketing in a recession," says Shara Rosen, Kalorama's lead diagnostics analyst. "But the reality is that to impress increasingly skeptical payers, they may have to spend more."

Published clinical trials comparing a new test with existing tests providing cost/benefit analyses and peer-reviewed evaluation of the technology help to persuade physicians to order the test and payers to pay for it. A new product that has gone through a cost/benefit evaluation is more likely to be awarded the higher reimbursement status essential for market penetration, particularly during a recession.

For more information, visit kaloramainformation.com.

SIX TACTICS FOR SUCCESSFUL IVD COMMERCIALIZATION

1. Strategic market planning: create a strategic marketing plan that allows for smooth market penetration while allowing for unexpected developments.
2. Intellectual property and patent protection: government-granted patents are essential to protecting a company's investment in developing new tests.
3. Regulatory process management: companies should determine the breadth of the product launch early in the design of the marketing plan and should assemble clinical data for regulatory approvals accordingly.
4. Reimbursement: ensuring adequate payer coverage immediately after or simultaneous with the market launch of a product is ideal.
5. Product life-cycle management: a company's strategic plan should include accommodation for manufacturing scale-up and a framework for creating the infrastructure needed to support sales efforts and customer service throughout the product life cycle.
6. Market forces management: product development and commercialization plans must incorporate factors such as competition, consumer power, and the needs and perceptions of investors and members of the medical and scientific communities.

Source: Kalorama Information, What is Working in IVD: Successful Commercialization of New Products and Technologies. For more information, visit kaloramainformation.com.

Market Research Key to Building Relationships with **MANAGED MARKETS PAYERS**

While biopharmaceutical companies still direct the bulk of their marketing and market research

KEYS TO IMPROVING MMMR OPERATIONS

- No single structure is optimal. Many structure types can work effectively for the MMMR function; a more critical success factor is the level of research staff knowledge and understanding of the managed markets sector.
- Manage resource competition. Brand teams and managed markets research projects generally have different targets (physician/patient vs. payer) and find themselves competing for resources and attention.
- Don't wait until it's too late to develop insights. MMMR activities peak during Phase III clinical development, though most benchmark partners are moving to push these into earlier phases.
- Expand account managers' roles to access managed market insight. Account managers are seen by most participants as the most reliable method for accessing hard-to-reach partners.
- Provide performance guarantees/warranties. About 80% of benchmarked companies have explored the concept of offering warranties, but most find their usefulness limited because of unpredictable patient compliance and complex Medicaid-related CMS submissions.

Source: Best Practices, Understanding Managed Markets: Effective Market Research Structures & Activities to Maximize Payer Access & Insights. For more information, visit best-in-class.com.

efforts toward physician customers, physicians are rapidly losing their influence over patients' drug utilization decisions. This is taking place as commercial and government payers gain importance.

According to Best Practices, it is estimated that third-party payers in the managed markets sector currently control more than 80% of patient access to prescription drugs in the United States. To succeed, pharmaceutical companies must access payers and build relationships to develop the best possible managed markets insights before product launch.

The recent Best Practices report, Understanding Managed Markets: Effective Market Research Structures & Activities to Maximize Payer Access & Insights, found that organizations with dedicated managed markets market research (MMMR) staff and budgets — regardless of departmental location — are likely to be more effective. A dedicated staff allows researchers to develop subject matter expertise; enables long-term or ongoing projects with regular updates; eliminates competition with brand teams for limited resource availability; puts the budget in the hands of the people asking the research questions; and reduces potential duplication of work.

Account management is the approach that best opens doors to hard-to-reach payers, with more than three-quarters (78%) of study participants ranking account management as highly effective for reaching payers. Other highly effective approaches cited by at least half of the respondents include one-off informational discussions with payers and peer-to-peer meetings between clinical experts, physicians, and contracting specialists.

None of the companies in the study gave high rankings to approaches involving mock P&T committees, peer-to-peer phone meetings between departments, in-person qualitative interviews/focus groups, or quantitative surveys via phone.

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

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Recession Forces **SENIORS TO CUT BACK ON MEDICINES**

According to a recent survey by The Senior Citizens League (TSCL), the recession is forcing U.S. senior citizens to make drastic cuts to their medical budgets.

The survey, conducted over a three-month period with more than 1,040 respondents 65 and older, found that 42% had either postponed filling their prescription medications or were taking a smaller dosage than prescribed by their physicians. In addition, 32% of respondents reported that their drug plan increased its co-pay or co-insurance in 2009, and 62% said they had cut back on doctor visits or outpatient services.

Since 2000, seniors have lost 20% of their buying power, according to an earlier TSCL study released in May. That trend will likely continue as senior costs continue to exceed the cost of living adjustment (COLA), and the Congressional Budget Office is forecasting no Social Security COLA in 2010 or 2011.

"Millions of seniors have been struggling to make ends meet for many years," says Daniel O'Connell, chairman of TSCL. "But this survey makes clear that the recession has made things go from bad to worse for older Americans."

For more information, visit seniorsleague.org.

Faster, More Cost-Effective Epigenetics Advances **PHARMA RESEARCH**

Over the past five years, renewed attention has been paid to the field of epigenetics as scientists piece together a molecular puzzle revealing how heritable information — other than the DNA itself — influences gene function. Breakthroughs in epigenetics have increased understanding of disease states and are becoming critical for advancing any field rooted in genetics, including pharmacogenomics. As more epigenetic markers are associated with specific diseases, tools can be developed to diagnose patients and gauge the severity of disease.

BioInformatics' recent study, Exploring the Epigenetics Market: Opportunities for Product Placement and Innovation, found that advances enabling faster and cheaper mapping of epigenetic modifications have accelerated discoveries in the field. While epigenetics research continues to employ such commonplace molecular biological techniques as restriction enzyme digestion, primer extension, and Southern blotting, it also involves more complex technologies such as DNA sequencing, real-time PCR, HPLC, and Matrix-assisted laser desorption/ionization–time of flight mass spectrometry. According to the study, in the next three to five years, respondents expect to increase the percentage of their efforts in the lab devoted to epigenetics research by an average of 10%.

For more information, visit gene2drug.com.

EFFECTIVE PATIENT COMMUNICATIONS PROGRAMS Rely on Appropriate Resources, Delivery Methods

With patients more actively seeking medical information, it is critical for pharma companies to provide objective and accessible knowledge about their products, using tools that effectively deliver the educational content to the appropriate audience. A successful patient-education campaign also depends heavily on appropriate resource support and allocation within the company.

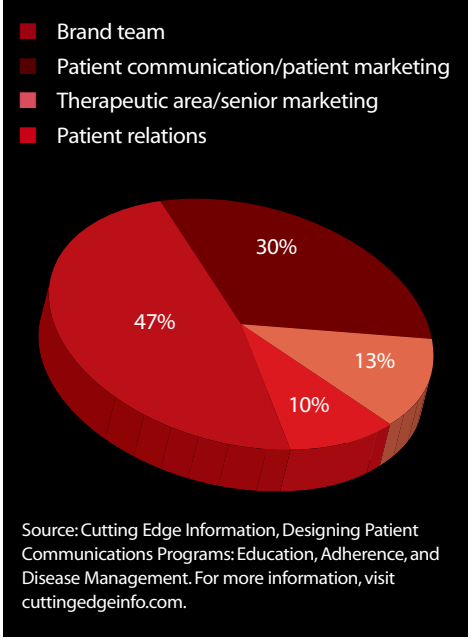
The recent Cutting Edge Information report, Designing Patient Communications Programs: Education, Adherence, and Disease Management, observes that while pharma brand teams continue to have the most input into one-on-one patient communications, patient communication and patient marketing teams are beginning to weigh in heavily as well. Both these teams have a stronger presence in one-on-one development than in developing print or Web-based communications tools, since one-on-one delivery remains a more effective delivery format for certain geographic and demographic populations.

For example, elderly patients typically benefit greatly from one-on-one consultation, due to their generally lower levels of computer proficiency and Internet access. Often, the elderly patient base does not view the Internet as a trusted information resource, so investment in Web-based communications, no matter how accurate, can be met with low return.

When measuring patient communications success, the report says that most brand teams choose from the following five ROI measurements: total prescription volume, new prescription volume, returned postcards volume, Website traffic, and call-center volume. According to the report, however, none of these techniques are likely to show a direct link to ROI for patient communications. For instance, new prescription volume and total prescription volume result from numerous other company activities, most of which have a more direct influence than patient communications. It is probably for this reason that some companies use other metrics in addition to the top-five to measure ROI, such as request-for-information e-mails, patient meeting attendance, and visits to patient centers.

For more information, visit cuttingedgeinfo.com.

GROUPS LEADING DEVELOPMENT OF PATIENT COMMUNICATIONS



Source: Cutting Edge Information, Designing Patient Communications Programs: Education, Adherence, and Disease Management. For more information, visit cuttingedgeinfo.com.

Industry is Meeting Timelines for **POSTMARKETING RESEARCH**

Makers of approved drugs and biologics generally are meeting their regulatory obligations and completing their postmarketing studies in a timely manner, according to a study released by the U.S. Food and Drug Administration. A review of 1,531 open postmarketing studies indicated that more than 80% are proceeding according to the established timelines, have been submitted for FDA review, or have been determined by the FDA to have met their goals or are no longer needed.

The study, done under a contract with Booz Allen Hamilton and supported by additional funds from Congress, examined the backlog of industry postmarketing studies for FDA-approved drugs and biologics. The review found that most companies meet their obligations in a timely manner.

The study also recommended changes designed to improve the quality of the information submitted to the FDA, the timeliness of the FDA review, and the accuracy of the FDA's databases.

"New resources and directives from Congress have allowed us to complete this long-desired review," says Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "The data indicate that makers of approved drugs and biologics are generally meeting their regulatory obligations and are on track with their studies. To date, we have not identified any previously unknown serious safety issues from the submitted final study reports."

For more information, visit fda.gov.

QUICK FACTS

- Drug companies spend an average of $102.8 million annually in market outlays to support a typical billion-dollar blockbuster. Large drug companies spend between $95 million and $154 million to market a successful blockbuster, while small drug companies can spend between $40 million and $121 million on marketing expenses for their blockbuster brands.

Source: Cutting Edge Information, Driving Successful Pharma Brands: Case Studies of Real Product Launches. For more information, visit cuttingedgeinfo.com.

- The market for antipsychotics had an estimated global value of $22 billion in 2008, and the novel and reformulated pipeline of atypical antipsychotics are expected to drive the growth potential of this market over the next several years. For example, Schering-Plough's Saphris (asenapine), recently recommended for FDA approval to treat both schizophrenia and bipolar disorder, is forecast to generate sales of $600 million by 2013.

Source: Datamonitor, Commercial Insight: Antipsychotics. For more information, visit datamonitor.com.

- Through 2018, generic erosion of key statins such as Pfizer's Lipitor (atorvastatin) and AstraZeneca's Crestor (rosuvastatin) will reduce the dyslipidemia drug market by $4 billion in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

Source: Decision Resources, Pharmacor report on Dyslipidemia. For more information, visit decisionresources.com.

- Although sales of emerging therapies are expected to partially offset losses to generic competitors, the migraine drug market is projected to decline from $4.7 billion in 2008 to $3.4 billion in 2018 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Generic erosion of top-selling triptans such as GlaxoSmithKline's Imitrex/Imigran will constrain the overall migraine market during the next decade.

Source: Decision Resources, Pharmacor report on Migraine. For more information, visit decisionresources.com.

- The estimated $2 billion growth in the prostate cancer drug market though 2018 will be driven principally by the launch of emerging therapies in the metastatic hormone-refractory population, most notably Dendreon's Provenge. Therapies in this category are expected to capture more than one-third of the overall prostate cancer drug market in 2018 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

Source: Decision Resources, Pharmacor report on Prostate Cancer. For more information, visit decisionresources.com.

- Because of its impressive effectiveness in treating rheumatoid arthritis, Rigel Pharmaceuticals' investigational novel oral agent fostamatinib disodium (R788) will likely precede TNF-alpha inhibitors such as Amgen/Wyeth/Takeda's Enbrel and Abbott/Eisai's Humira in the treatment cascade for rheumatoid arthritis. But uncertainties about its efficacy in the TNF-refractory population and the absence of a head-to-head trial against a TNF-alpha inhibitor lead to lower sales expectations than Pfizer's Jak-3 inhibitor CP-690550. Conservative forecasts are for a gain of up to 1.8% patient share and major-market sales of $330 million in 2018.

Source: Decision Resources, Pharmacor report on Rheumatoid Arthritis (updated). For more information, visit decisionresources.com.

- The entry and uptake of premium-priced biologics such as Human Genome Sciences/GlaxoSmithKline's Benlysta, Biogen Idec/Roche's ocrelizumab, and Immunomedics/UCB's epratuzumab is projected to propel the systemic lupus erythematosus drug market from about $420 million in 2008 to nearly $2 billion in 2018.

Source: Decision Resources, Pharmacor report on Systemic Lupus Erythematosus. For more information, visit decisionresources.com.

- About 76% of surveyed pharmacy directors say by 2014 they expect their managed care organization will have only one preferred biologic for all immune conditions, such as rheumatoid arthritis, psoriasis, Crohn's disease, and ulcerative colitis. Centocor Ortho Biotech's Remicade and Abbott's Humira stand to most directly benefit from this strategy, as these drugs are currently marketed and/or in development for multiple indications.

Source: Fingertip Formulary, Formulary Advantages in Immune Biologics: Tightening Payer Control Offers Opportunities for Differentiation. For more information, visit fingertipformulary.com.

- Rising public awareness of breast cancer and available treatments have increased revenue in the breast cancer therapeutics market in Australia. As the most common cancer diagnosed in Australia's female population, the total number of breast cancer patients in the country was 164,814 in 2008; this figure is estimated to reach 304,511 patients by 2013.

Source: Frost & Sullivan, The Breast Cancer Therapeutics Market in Australia. For more information, visit frost.com.

- Fierce competition could open up between producers of generic biopharmaceuticals — widely known as biosimilars — and branded biopharmaceuticals if Congress approves approves a regulatory pathway for these drugs in the United States as expected in 2009. U.S. approval would unleash the efforts of a few experienced and strongly funded competitors, creating a U.S. market for biosimilar drugs that could reach $45 million by 2015.

Source: Kalorama Information, Drug Delivery Markets: Oral Delivery. For more information, visit kaloramainformation.com.

- The worldwide market for oral drugs using drug delivery technologies reached revenue at the manufacturer level of $43 billion in 2008 for both major technologies in oral delivery and the products that use these delivery technologies. The market is expected to reach $71 billion by 2013, with a compound annual growth rate (CAGR) of almost 11% for the five-year period beginning in 2009.

Source: Kalorama Information, The World Market for Biosimilars and the Potential for U.S. Follow-On Biologics. For more information, visit kaloramainformation.com.

- The total drug-device combination market is expected to be worth $18.54 billion by 2014, out of which the U.S. market will account for almost 30.9% of the total revenue. The global market is expected to record a CAGR of 11.8% from 2009 to 2014.

Source: MarketsandMarkets, Drug-Device Combination Market (2009-2014). For more information, visit marketsandmarkets.com.