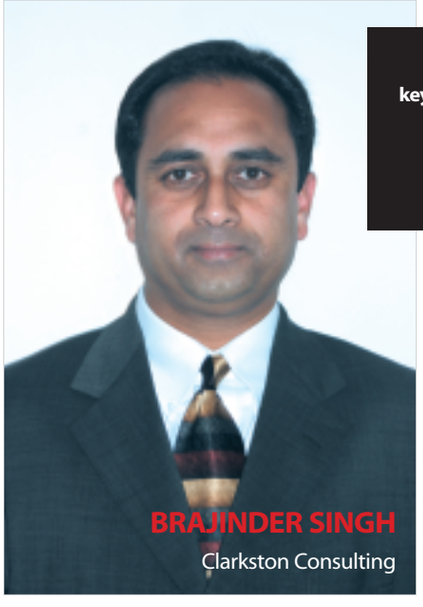
BY TAREN GROM and DENISE MYSHKO

Tracking the Trends THE INDUSTRY across Sectors

FROM THE CLINIC TO THE MARKET TO THE BOARDROOM, a plethora of factors are expected to change the healthcare landscape in the coming year and beyond. More than 135 distinguished industry executives, representing all of the major sectors of the life-sciences industry, provide their insights on the hot topics and discuss how these market shapers are expected to influence business, strategies, and the bottom line in 2006.

A distinguished list of more than 135 industry executives raise their voice.



BRAJINDER SINGH
Clarkston Consulting

In 2006, pharmaceutical leaders will start to adapt key best practices of the consumer goods industry to move to an adaptive supply-chain model that will increase product speed to market and revenue, decrease costs, and enhance operational efficiencies.

All points along the continuum — from drug discovery to Medicare to marketing and sales to supply-chain management — will be impacted by current and emerging market forces.

AITKEN. Several key market events are expected to shape the pharmaceutical industry in 2006. These include the introduction of the Medicare drug benefit in the United States, expected patent loss and generic introduction for six blockbuster products, and continued efforts by local governments to reduce drug spending and manage patient access to branded pharmaceuticals. While some pharmaceutical companies are taking the necessary steps to address these areas, others must start planning now to ensure continued growth and success. Collectively, the pharmaceutical industry must continue its efforts to enhance its public image and demonstrate its commitment to the advancement of healthcare. The pharmaceutical industry must carefully consider how to adapt its business model to sustain growth worldwide. Market conditions are changing, the government's span of control is growing, and future success will only be achieved by those manufacturers with innovative products, demonstrable cost-effectiveness, and productive, evidence-based sales and marketing approaches.

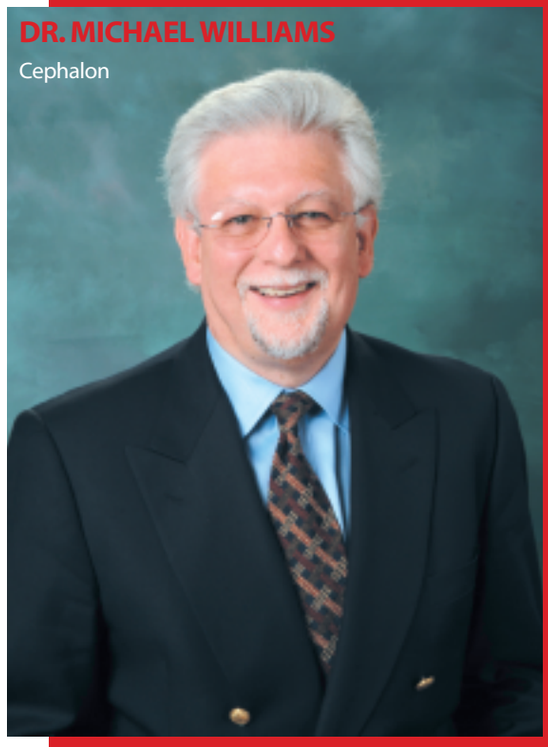
KAITIN. The number of new drug approvals by the FDA has fallen, and the average clinical times for priority drugs are at their longest since before enactment of PDUFA. As drug development becomes more complex and

MEDICINE USE STATISTICS AT A GLANCE

- **By 2010**, the number of retail prescriptions is projected to reach **4.5 billion**; in 2003 the number of prescriptions was **3.22 billion** accounting for **$203.1 billion** in sales.
- The elderly (ages 65 and older) account for **13%** of the U.S. population and **34%** of all prescription medicines dispensed and for **42%** of retail prescription expenditures.
- The average number of prescriptions per elderly person is predicted to reach **38.5 by 2010**, compared with about **28.5 in 2000**.
- By 2010, **95%** of patients should receive from their prescribers and pharmacists verbal counseling on appropriate use and potential risks of medications. In 1999, based on an eight-state study of community pharmacies, **87%** of patients received written information with their prescriptions; only **35%** of pharmacists made any reference to the written leaflet; and only **8%** actually reviewed it with the patient.
- Researchers found a **76%** discrepancy rate between what medicines patients were prescribed and what medicines (Rx and nonprescription) they actually took. Of those discrepancies, **51%** stemmed from patients taking medicines not recorded; **29%** were from patients not taking a recorded medicine; and **29%** were from differences in dosages.
- More than half of medication-related injuries identified in a study of **18** community nursing homes were preventable. Psychoactive drugs (antipsychotics, sedatives, antidepressants, and hypnotics) were the most common medications associated with preventable adverse drug events (ADEs), the researchers found. Given the country's **1.5 million** nursing home residents, if the findings are extrapolated, then at least **350,000** ADEs occur each year, more than half of which are preventable.
- Among Medicare beneficiaries, **87%** need to fill at least one prescription each year. More than half (**56%**) of these beneficiaries use prescription medicines costing **$500** or more; and **38%** require medicines costing **$1,000** or more. One in three Medicare beneficiaries has no prescription drug coverage.

Source: National Council on Patient Information and Education, Bethesda, Md.
For more information, visit talkaboutrx.org.

Analysis of success rates for pharmaceutical companies, from first-in-man to registration, indicate that the average for all therapeutic areas is about 11%. Only one in nine compounds makes it through development and receives approval. Nonetheless, drug discovery remains the foundation on which the pharmaceutical industry has introduced innovations for improving health.



DR. MICHAEL WILLIAMS
Cephalon

expensive, developers tend to concentrate available resources on fewer projects. Fewer development projects, in turn, lead to fewer new drug approvals.

WILLIAMS. Modern drug discovery has become exceedingly challenging, as dramatic decreases in new product approvals have characterized the pharmaceutical industry in the last decade. Analysis of success rates for pharmaceutical companies, from first-in-man to registration, indicate that the average for all therapeutic areas is about 11%. Only one in nine compounds makes it through development and receives approval. Nonetheless, drug discovery remains the foundation on which the pharmaceutical industry has introduced innovations for improving health.

CARR. It's a cliché now to invoke "complexity theory" to describe the world of pharma. But if one reads mathematical papers in the field, we know that complex dynamic systems behave according to the principle of self-organized criticality. Like grains of sand piling up on the bottom of an hourglass, complex systems continually strive to become slightly more ordered than their infrastructure can support. In an hourglass, the slope of the sand pile is always just as high, or slightly higher, than the pile can sustain. The result is a continual series of small avalanches interspersed with occasional larger avalanches. DeToqueville, writing in the early 19th century on American democracy, warned of the danger

Thought **LEADERS**

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that the proliferation of rules and regulations could one day weaken, even paralyze, this robust young nation. The growing number of rules within which American pharma companies operate strikes me as a case study in self-organized criticality.

GREY. In its never-ending quest for ways and means to shorten the development life cycle and bring greater efficiencies to the clinical trials process, pharma companies and CROs are now adopting optimization technologies on a grander scale. Several unique applications have emerged to address the biggest process hurdles: remote site management, trial status visualization, trial remediation decision-making, investigator recruitment, and patient recruitment.

BAKALOV. There are two issues that pharmaceutical companies should focus on during the next couple of years. The first is sustaining the efforts to meet regulatory compliance and the second is leveraging the opportunity created by compliance to evolve the information security function into a strategic capability. The sheer number of regulations, particularly in pharma and biotech, and the stiff penalties of not complying with them have brought information security into the boardroom. Yet many organizations are missing the rare investment opportunities that compliance offers to promote information security as an integral part of their business.

HOLLINGSWORTH. Pharmaceutical, biotechnology, and medical-device companies are stepping back and rethinking their clinical-data management system needs. Implementing a software application in one facility

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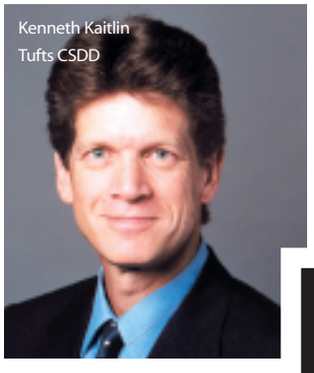
NEW DRUGS TAKE LONGER TO BRING TO MARKET IN THE UNITED STATES


Kenneth Kaitlin
Tufts CSDD

Longer clinical times are extending the time it takes to bring new prescription drugs to market in the United States, according to analysis recently completed by the Tufts Center for the Study of Drug Development (CSDD).

Lengthening the average clinical phase times has offset the gains made by shorter approval phase times since the passage of PDUFA.

The study found that new **medicines that win approval** from the FDA **required** an average of **8.5 years** to move through the clinical and approval phases in the 2002 to 2004 period.

This contrasts with a steady decline in combined clinical and phase times since passage of the Prescription Drug User Fee Act of 1992 (PDUFA) — from a high of **9.4 years in 1990 through 1992 to 7.2 years from 1999 through 2001**, according to the Tufts CSDD analysis.

According to Kenneth I. Kaitin, director of Tufts CSDD, lengthening average clinical phase times has offset the gains made by shorter approval phase times since the passage of PDUFA.

PDUFA, which generally has been considered a success, allows the FDA to collect fees from drug companies to be used, in part, to hire additional reviewers and improve the drug review process. PDUFA was reauthorized in 1997 and again in 2002.

THE TUFTS CSDD ANALYSIS, SUMMARIZED IN THE NOVEMBER/DECEMBER TUFTS CSDD IMPACT REPORT, ALSO FOUND THAT:

After a spike in new drug approvals in 1996 through 1998, due in part to the FDA's clearing its backlog of applications, **total approvals dropped 47%** between 2002 and 2004.

Clinical phase times have increased for most therapeutic areas between 1999 and 2001 and 2002 through 2004.

In recent years, drugs for **neuropharmacologic diseases have taken the longest** to develop and bring to market.

Source: Tufts Center for the Study of Drug Development, Boston. For more information, visit csdd.tufts.edu.

DR. MARK GOLDBERG

Perceptive Informatics

The definition of a good outsourcing partner to smaller bio/pharma companies will continue to evolve in 2006 and beyond. It will be increasingly important for CROs to streamline communications with their clients, taking advantage of appropriate technologies.

may fix a short-term problem, but a global strategy that includes process modeling, training, and change management will increase product speed to market and develop a strong competitive advantage that can reshape a manufacturer's market position.

NOFFKE. While the issues confronting the industry are daunting — including drug safety, increased regulatory conservatism, and reduced R&D productivity — good project management can help meet these challenges. Project management can condense project schedules, control costs, and produce high-quality results by ensuring projects are performed with precision and that any obstacles arising midstream are addressed promptly. While project management happens at the team level, it is very much linked to strategic issues discussed in the boardroom. More senior executives are recognizing this reality and using project management as another tool in their arsenal to enhance their competitive positions.

SHIELDS-UEHLING. Pharmaceutical and healthcare industries must reduce their reliance on paper. An estimated 40% of all pharmaceutical R&D costs are attributed to paper-based business processes. A recent estimate puts U.S. healthcare R&D spending at $95 billion per year (JAMA); $54 billion of that is by the biopharmaceutical industry. Standards, such as SAFE, are essential to ensuring regulatory compliance and accelerating cost savings and greater efficiencies. As biopharmaceutical organizations strive to improve productivity and reduce costs in clinical trials, their attention turns increasingly to electronic clinical research and healthcare transactions. In particular, streamlined processes for electronic information exchange and identity assurance present a golden opportunity for these organizations to reap time and cost savings from decreased paper management, improved operational efficiency, and increased productivity. Using Secure Access For Everyone (SAFE), the global standard that enables secure and legally enforceable paperless business and clinical transactions, biopharmaceutical organizations can develop an identity assurance model to automate the registration process for clinical investigators and remove paper-based latency and infrastructure costs.

IMS GLOBAL PHARMACEUTICAL MARKET FORECAST FOR 2006

The U.S. market, which accounts for 43% of pharmaceutical sales worldwide, will continue to fuel growth in 2006.

The U.S. market will increase at a **8%** to **9%** pace, up from an expected growth of **6%** to **7%** in 2005. Increased access by U.S. seniors to lower-cost medications through Medicare Part D and a rebound from the impact of Cox-2 product recalls and safety issues will help support this higher level of growth.

Growth for the five major European markets — France, Germany, Italy, Spain, and the United Kingdom — is forecast to be **4%** to **5%** in 2006, down slightly from this year. Expansion of the reference price system and mechanisms to encourage generics use are expected to impact growth. This will be partially offset by the higher spending on public health and disease-awareness programs and the launch of innovative products.

THE LARGEST MARKETS IN CENTRAL AND EASTERN EUROPE CAN EXPECT DOUBLE-DIGIT GROWTH in 2006 as healthcare systems are modernized and GDP growth helps finance increasing demand.

THE JAPANESE MARKET WILL EXPERIENCE A DOWNTURN in 2006, with forecasts showing from **0%** to **1%** growth, down from the **5%** to **6%** growth expected in 2005. This reflects the impact of restrictive National Health Insurance reimbursement listings and biennial price cuts.

CHINA CONTINUES TO EMERGE as a significant market. Growth will remain robust at **17%** to **18%** and the market size will reach $13 billion to $14 billion in 2006. Strong economic growth and the continued implementation of the national reimbursement drug list will sustain high market growth, offset somewhat by price cuts and tighter cost-containment measures.

THERAPEUTIC FORECASTS

Among the major therapy classes, **oncology** will register the highest global growth rate of **17%** to **18%** in 2006, fueled by the rapid uptake of some recently launched breakthrough products that include Avastin, Erbitux, Alimta, and Tarceva, as well as increased patient access to these innovative treatments.

The **statins class** will show growth of **7%** to **8%** despite the increasing availability of generic forms, as evidence of their efficacy and as clinical guidelines expand the potential patient population that would benefit from these treatments.

ABOVE-AVERAGE GROWTH ALSO IS EXPECTED in the angiotensin-II, platelet aggregation inhibitors and osteoporosis classes, fueled by the uptake of new products and availability of new clinical evidence.

MANUFACTURER IMPLICATIONS

Pharmaceutical manufacturers must take decisive action in a number of areas to respond to the changes in market conditions and shifts in their product portfolios. These actions include:

- **REASSESSING** sales and marketing spend levels and practices
- **ACCELERATING** safety surveillance efforts
- **INVESTING** in health outcomes and pharmacoeconomic studies to prove the value of medications
- **PURSUING** growth in emerging markets such as China, Latin America, and Eastern Europe

Source: IMS Health, Fairfield, Conn.
For more information, visit imshealth.com.

DAVID WOOD

Interbrand Wood Healthcare

The marketing and sales machines of big pharma must be fed, so the race is on to license in and purchase compounds wherever they can be found. The age of big pharma and blockbusters as we know it will either be changed dramatically or will disappear.

WOOD. The marketing and sales machines of big pharma must be fed, so the race is on to license in and purchase compounds wherever they can be found. The age of big pharma and blockbusters as we know them will either be dramatically changed or will disappear. One also has to question how much longer the salesforce will be the principal means used by pharma to sell its drugs.

SINGH. In 2006, pharmaceutical leaders will start to adapt key best practices of the consumer goods industry to move to an adaptive supply-chain model that will increase product speed to market and revenue, decrease costs, and enhance operational efficiencies. Creating a supply chain that easily lets pharmaceutical manufacturers navigate the changing market waters with their expanding distribution will be a competitive advantage for the early adopters.

GOLDBERG. An important trend to watch in 2006 will be the continued increase in development activities by small and emerging bio/pharmaceutical companies. For the outsourcing industry, this means more opportunity as smaller companies are less likely to establish full development organizations. Emerging companies often require a broad range of expertise from outsourcing partners to take scientific discoveries through development and ultimately to commercialization. Additionally, these companies increasingly need partners with global presence as more trials are executed outside of North America and Western Europe.

LAFLEUR. As the industry digs deeper into a do-more-with-less reality, so follows marketing and promotions. The challenge is to keep shrinking budgets from translating into shriveled brands. Creative experts can take a great brand beyond just good-looking logos and masterful Photoshop techniques and amplify communications above the noise of every other creative concept hitting the market by striving for "smartcreative" — creative that strategically integrates the product's own unique science with a uniquely creative brand idea, and achieving the balance of compelling credibility and vibrant visibility. Fortunately, "smartcreative" is becoming a reality through an evolving agency model that strategically aligns the science storytellers with the creative visionaries. Although the do-more-with-less reality can downsize anyone's big brand plans, focusing on fusing science and creative will maximize brand success.