CRYSTAL BALL

What the Future Holds

As PharmaVOICE presents its third annual Year in Preview issue, we asked our readers to look forward and provide us with their insights on the hot issues, topics, and trends that they think will impact the life-sciences/pharmaceutical industry in 2007.

This is their chance to gaze into their personal crystal balls and identify what their visions are for 2007 and beyond.

An Educated Patient is the Best Customer

There is increasing pressure to demonstrate a benefit-to-cost ratio and increased pressure and expense to address safety issues both pre- and post-marketing. The industry needs to educate the public and the media about the long development times, high costs, and high risks that are unique to the biopharma industry.

Una S. Ryan, Ph.D.
President and CEO
AVANT IMMUNOTHERAPEUTICS INC.

Reinventing the Sales Model

Over the next year, I believe the industry will be faced with the challenge of reinventing some of its most fundamental business models to meet the needs of a changing market. Perhaps the most radical, but also the most essential, change will be the need to transition from a sales model to a service model. To continue succeeding, companies must expand their focus from simply measuring the performance of sales processes to increasing the value of physician relationships. They will need to go beyond traditional product selling to a true service orientation and create integrated physician experiences that build long-term emotional connections between doctors and brands.

While quality details are still important, they are no longer enough to address physicians' needs and secure their commitment. Both PCPs and specialists now say they are seeking a new mix of experiences from pharma companies. In particular, they are looking for patient-management support and educational/information services to support their practices, as well as knowledgeable and experienced reps. Successful companies will need to be both educators and business partners to build the strong ties with physicians that ensure high commitment and ongoing prescribing. They will need tools that guide them to the right balance of sales and service activities.

That need to build long-term, committed relationships is just as important in DTC and physician selling. Committed consumers are twice as likely to ask physicians for their preferred brand, give more of their business to their preferred brand, are less likely to defect (and, in fact, don't even listen to competitive DTC messages), are more likely to be active advocates for a brand, and are more likely to visit the brand's Website to seek out supporting positions. Visiting a brand's Website is an important step as our research shows it can increase intent to contact a doctor by as much as 50%.

This focus on building new models that drive commitment is coming at a truly exciting time for pharmaceutical brands. With the advent of DTC and the Internet, many of today's pharmaceutical brands, such as Lipitor, Ambien, and Viagra, have achieved the household-name status once only reserved for the consumer giants, such as Apple and Coke.

Pharma brands now have the kind of brand equity that make it critical for them to be managed as significant business assets and that means finding new brand architecture models that support brand power and value, even beyond the patent period. As an example, companies may want to consider building "master brands" within a category, such as lifestyle drugs, for all its entries in that area. That would allow the brand value to live on, even after the patent on a specific product expires.

There is a wealth of new models that pharma marketers will need to consider to ensure their brands achieve their optimal potential. Key to the process will be expanding their vision beyond the patent period. If they limit their opportunities to the original chemical's patent, they will leave huge amounts of potential revenue on the table.

Elaine Riddell
CEO
TNS HEALTHCARE

Global Trial Outsourcing

Over the next few years we expect to see an increasing trend in the outsourcing of large global studies, further strengthening the relationships between biopharmaceutical companies and the CRO sector. The ability to connect experienced resources across the globe to deliver customized solutions, leveraging expertise in multiple therapeutic areas and geographies, will be key to the success of these relationships. By offering solutions in both traditional and emerging markets such as Latin America, Central and Eastern Europe, Asia/Pacific, and Africa, we can support the increasing demands in global clinical development.

Simon Higginbotham
VP and Chief Marketing Officer
KENDLE

Following a Path to Success

With the objective of modernizing the drug-development process by 2010, the FDA's Critical Path Initiative (C-Path) seeks to couple new study methodologies, such as adaptive trial design, with specialized biomedical informatics data technology systems enabling drug developers to make better decisions faster and

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increase patient safety, while reducing the time and overall development costs to bring new drugs to market. INC Research is proactively moving to incorporate these new strategies to provide our customers with the flexibility they require to meet the era of personalized medicine in the 21st century. Interesting times.

John Potthoff, Ph.D.
Chief Operating Officer
INC RESEARCH INC.

State of Information Security

On average, U.S. pharmaceutical companies and life-sciences firms, including biotech, biomedical, and medical-device firms report that they will spend 14.4% and 21.3%, respectively, of their information technology (IT) budgets on security and privacy this year. By comparison, the average spending on security and privacy is 12.9% of IT budgets across all U.S. industries and 17% for all industries.

Six of 10 U.S. pharmaceutical companies and four of 10 life-sciences firms say their spending on information security increased this year over last, with 21% of pharmaceutical firms and 19% of life-sciences companies increasing spending by double-digit rates. Seventy-eight percent of pharmaceutical companies and 71% of life-sciences firms said business continuity and disaster recovery are driving their increased spending on information security. This is understandable in light of ever-more stringent state and federal privacy requirements and as market forces and government regulations push these industries toward increasing levels of automation and information access.

About four in 10 pharmaceutical companies and life-sciences firms said reputation management also is a driver of increased spending on security. Pharmaceutical and life-sciences firms are in a constant firefight, reacting to new regulations or security breaches as they arise but rarely do they have the time to craft an overall battle plan.

Pat Roche
Partner
PRICEWATERHOUSECOOPERS

Process Re-engineering

Like the ancient sages who could read tea leaves and foretell the future, we can follow the tea-leaf patterns in the happenings of the pharma and biotech industry over the last five years and attempt to foretell the future of the industry. The coming year will be, as I term it, "the year of reinnovation and globalization."

Reinnovation signifies a resurgence of a better understanding of the building blocks of life. The industry's ability to harness this knowledge in designing new therapeutics will have a major positive impact on the health of people. The logarithmic pace of knowledge creation and its ability to unravel the mysteries of life has resulted in the industry re-engineering the process of how a disease could be treated, controlled, and prevented. These advances will change the disease treatment paradigm as we currently know it.

Globalization will ensure that medical treatments will benefit everyone on the planet. Much like Tom Friedman's insight on the globalization of information technology in "The World is Flat" and its impact, healthcare innovation and advancements will truly leverage this connectability in the flat world and accelerate new therapeutic treatments and cures to the illnesses of the world.

Ravi Kiron, Ph.D., MBA
Pharma/Biotech Strategy Executive
FORMERLY WITH ALZA CORP.

Postmarketing Safety Issues

As a company focused on postmarketing, we have seen an increasing interest from both sponsors and the FDA in active surveillance programs, especially safety registries, in the postmarketing phase for new molecules and for drugs and devices with blockbuster potential.

One of the biggest trends that will impact drug development will come from outside development, for example postapproval. The idea of "conditional approval" periods will be much more seriously looked at in 2007. This concept would allow earlier approvals of some drugs and biologics with a conditional approval phase where the drug would be monitored closely through registries and other surveillance mechanisms.

This concept has been presented by multiple stakeholders — from academia to industry to regulators — and offers the twin advantages of potentially decreasing time and cost to initial approval and increasing the ability of the FDA to monitor the safety profile of newly released drugs. The models for this exist within the fast-track concepts already used for approving some biopharmaceuticals.

We are seeing tremendous growth in the number of patient registries during the drug-development phase during which companies are seeking to understand the background safety signal before they introduce a product in a particular disease area, as well as the impact on safety and effectiveness after the product is launched.

Richard Gliklich, M.D.
CEO
OUTCOME

Mergers and Acquisitions

M&A activities and deal flow will continue to accelerate in 2007. Most large pharmaceutical companies continue to express strategic objectives to develop pipeline opportunities through acquisitions or collaboration activities. Recent examples — such as Eli Lilly's acquisition of biotech partner Icos, acquisitions by Pfizer, Johnson & Johnson, and Abbott, as well as activity in the biotech sector by Gilead — are evidence of a robust marketplace. Many pharmaceutical and medical-device companies have a number of opportunities in the pipeline that could lead to collaboration with viable partners providing either financial, research, or marketing resources. In their earnings releases, senior management often speaks of active pursuit of development and opportunities. While 2006 will come in as one of the most active in recent years, 2007 could prove to be even more dynamic.

John Rhodes
Global Sector Leader, Life Sciences, Life Sciences & Health Care Practice
DELOITTE & TOUCHE LLP

Life-Cycle Management

Life-cycle management through strategic improvements to packaging, delivery devices, or formulations of existing therapeutics can help ensure that a molecule's commercial potential is fully realized. There are a number of short- and long-term options for extending a product's life cycle, with package enhancements on one end of the timeline and product reformulations on the other.

Using these life-cycle management strategies effectively can yield tremendous value for the brand. At one time, these strategies were employed closer to the end of a molecule's patent; but in highly competitive therapy classes, companies are now employing "rolling" life-cycle management, which involves planning for new presentations and formulations in advance of a product's first launch. High-profile examples of this approach include several biologics in the rheumatoid arthritis and psoriasis markets.

Donna Williams
VP, Marketing, BioPharma Solutions
BAXTER HEALTHCARE CORP.