What's Your Opinion?

2005 — A LOOK AHEAD

What are the most significant business challenges you believe the industry will face in 2005?

Advocating value

Pharmaceutical industry professionals must advocate the value of pharmaceutical drugs to patients. Consumer groups, journalists, politicians, and consumers are shouting pharmaceutical prices are too high. What is the industry doing to combat these claims? The industry must communicate the value behind the pill: what is this ACE inhibitor, or NSAID, or antidepressant worth to you, the patient?

Lynn Gale, MBA
Account Manager
/alert Marketing

never been more obvious that it is crucial for the pharmaceutical industry to establish a credible, powerful voice in the public debate. The pharmaceutical industry needs to communicate to the public that it is on the same side. A key way to establish this credibility is for the pharma industry to show its commitment and lead the way in providing fair and balanced patient and healthcare provider education.

RISK MANAGEMENT

TURETT. The term risk management implies a defensive, prepare-for-the-worst strategy. While defensive preparation is certainly important, taking a fresh look at conducting business in a "patient-first" manner will reduce the need to implement a defensive approach. In other words, while the doctor is a key customer, the best interests of the person taking medications need to be the first priority every step of the way.

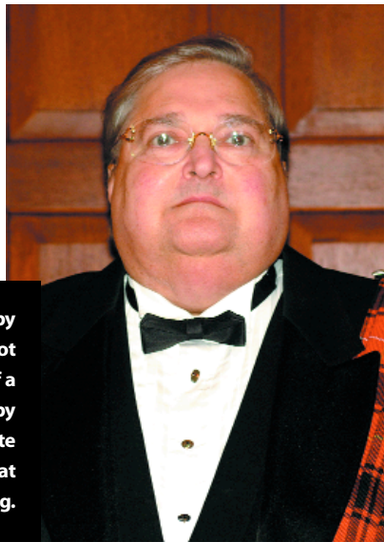
VAN MANEN. After the initial introduction of legislation concerning the development and use of pharmaceutical products and medical devices, the regulations and guidelines have become increasingly strict and detailed over time. But a problem associated with rules and guidelines is that they often have a tendency to become goals in themselves, without due regard to the reasons they were created in the first place. In the world of pharmaceutical and medical-device regulations and guidelines, the risk-management approach can be seen as an attempt to bring back the focus to the original goal as well as to broaden the scope to encompass aspects that previously had not been addressed. As one of the five strategic initiatives established within the FDA, risk management can be expected to receive ample attention in 2005 in establishing internal performance goals for the organization and as a basis for proposed rules and regulations, such as the proposed Safety Reporting Requirements for Human Drug and Biological Products, also known as "The Tome."

ERICKSON. For devices, "risk" or "hazard" analysis is already part of the development process. In the drug arena, targeted drugs should have much better therapeutic indices and improve the risk/benefit trade off. A great phrase I once heard is, "all drugs are poisons with beneficial side effects." That has certainly been true of chemotherapy agents. Maybe someday we will say, "all drugs are beneficial if properly prescribed based on sound diagnostics."

OWINGS. Expedient and solid implementation of a risk-based, science-based approach to clinical research, validation, and manufacturing though the adoption of data standards and new technologies will prove to be important and essential if a company is to compete in the heightened regulatory environment of the 21st century. The good news is government, academia, and industry are working together more than ever to accelerate research through the implementation of standards and initiatives that encourage the use of new technologies.

HAMELIN. One of the things that may occur in 2005 is actually a result, unfortunately, of what we have seen with Merck and the recall of Vioxx, which was pulled from the worldwide market in early October. This is a compound that was exposed to more than 100,000 patients in bona fide Phase III and Phase IV clinical trials; this is an enormous amount of clinical-trial data. Yet after five years on the market, we are still learning the nuances about the safety of this drug and its risk-benefit profile. This has significant implications at the regulatory level as well as for other aspects of the industry. Regulators may shift their mindset and require bigger and more extensive Phase III trials and more elaborate filing dossiers. The thinking may be that if one of the best companies in the world, Merck, can run into problems what's to prevent a similar event from happening with smaller, less experienced companies. This could turn into an enormous problem for the industry, especially for smaller pharmaceutical and biotech companies.

HADDOX. Today, most pharmaceutical companies have nascent risk-management programs. Given the current FDA guidances in this area along with the recent removal of Vioxx from the market and the subsequent congressional hearings, I would expect that risk-management programs will mature significantly in 2005. By year-end 2005 or early 2006, some clear direction on best practices should begin to emerge. For our part, Purdue Pharma formalized all of its risk-management activities under the umbrella of a Risk Management Program (RMP) in mid-2002. The RMP for our opioid products has four primary goals: ensure appropriate patient selection and proper use, minimize abuse, reduce diversion, and avoid inadvertent pediatric exposure. This process includes assessing risk, characterizing events, designing and deploying specific interventions both proactively and reactively, and assessing the effect of the interventions. To learn what risks are actually occurring once our products are on the market, we created the Researched Abuse, Diversion, and Addiction-



DR. W. LEIGH THOMPSON
Profound QualityResources Ltd.

Risk-benefit assessments are made by regulators for populations not individuals. To the individual dying of a disease whose life might be improved by a safe therapy, the equation looks quite different and we should not deny that patient the opportunity to try a drug.

Expedient and solid implementation of a risk-based, science-based approach to clinical research, validation, and manufacturing through the adoption of data standards and new technologies will prove to be important and essential if a company is to compete in the heightened regulatory environment of the 21st century.

MICHAEL OWINGS
Phase Forward

ROBBERT VAN MANEN
Phase Forward

Risk management will be an important explicit or implicit component of both new and modified regulations and guidelines, those originating from authorities (FDA, EMEA) as well as those from international organizations (CIOMS, ICH).

STEVEN KRIEGSMAN
CytRx Corp.

The FDA's efforts to create a new generation of performance standards will help to more accurately determine the risk-benefit ratio for a given therapeutic for a given indication, thus expediting approval.

DR. DESTRY SULKES
Medsn

Many medications carry risk and need a carefully managed communications strategy to minimize associated risks. Successful implementation of such strategies requires a cost-effective approach with documentation and tracking of the program's distribution and uptake.

Related Surveillance System (RADARS) to track abuse, addiction, and diversion of seven major opioid medications. We believe RADARS is the most advanced method of accumulating abuse and diversion data ever developed by a pharmaceutical company.

ERICKSON. Many politicians like to talk about the wonderful breakthroughs in medical science, but they seem to forget that turning science into products is done by companies and "greedy" capitalists who see opportunity despite the huge hurdles. Pricing pressures and increasingly expensive and longer development timelines, or both, reduce rates of return of innovative products and result in many programs being eliminated.

CAUWENBERGH. There is a need to streamline development, review, and approval processes according to realistic standards while avoiding protectionistic reflexes. Companies need to differentiate between real measures and processes to protect patients and processes that add no value. And they need to avoid interference from certain authorities in the actual strategic positioning of a new drug through excessive control on protocol design.

SALESFORCES

STERN. We are not doing a good job of listening to our customers when it comes to the number and quality of the sales representatives that we employ to sell our drugs to physicians. A 2003 Accel Healthcare study showed that we are letting our customers down; 60% of doctors believed that reps were younger and more aggressive than in the past. Most doctors want new, pertinent, reliable, timely, and unbiased information about products but believe that less than 50% of pharma reps provide these data to them; 62% of doctors want to receive balanced information they can trust, but only 6% said they received such information from pharma reps. One of the reasons that access to physicians continues to be a problem for our representatives is because we are putting too many feet on the street. Doctors are tired of seeing three, four, and five repre-