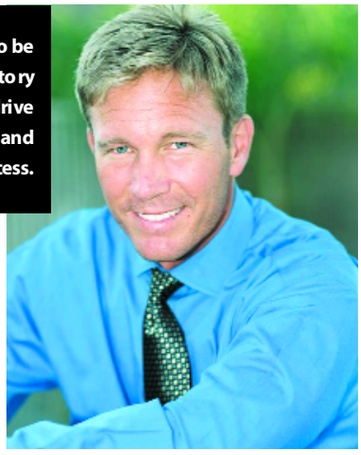
It is up to industry leaders to be aware of all the changing regulatory requirements. This will help drive efforts for a more uniform and transparent review process.



MICHAEL WILHELM
ImmuneRegen BioSciences Inc.

MICHAEL ASTRUE
Transkaryotic Therapies Inc.

We need a FDA commissioner who will push advisory committees to set standards for approval before companies invest years and tens of millions of dollars in clinical trials, not afterward.

The FDA is effectively increasing the hurdles companies must face to reach product approval by adding steps in the development process. While the information might prove useful, it will add years and significant costs to the development of new products.

DR. BRAD THOMPSON
Oncolytics Biotech Inc.

Companies need to avoid interference from certain authorities in the actual strategic positioning of a new drug through excessive control on protocol design.

to justify the cost of really innovative and large controlled clinical studies.

KOVAC. The requirements issued by the FDA for pharmaceutical and biotechnology companies to maintain formal records of specific transactions throughout the value chain will certainly become a sizable challenge in 2005 and years following. The FDA's plans to apply the doctrine of strict liability, under the Federal Food, Drugs and Cosmetics Act, as well as personal liability for CEOs and CFOs for compliance failure under the Sarbanes-Oxley Act are driving the transition to digital records management to better manage risk. Increasingly stringent regulatory requirements, patent infringement or patent interference suits, and product liability suits will stimulate the development and governance of digital record management systems that help companies comply with the regulations, protect their intellectual property, and limit their financial exposure.

W. LEVY. Harmonization of regulatory requirements should continue to be a top priority. Consistent requirements on a global basis will lower the cost of drug development. A rational policy must be developed for testing and approving products that are identical to existing products except that they are made using biotechnological processes. For too long, biotech products have been treated differently from products made by any other technology (the ANDA route is not available) and a policy must be established to deal with this issue. Also, continuing to streamline the approval process bears further attention.

REPUTATION ENHANCEMENT

AHN. The biopharmaceutical industry has blindly relied on the argument that high prices are needed because of increasing research and development costs. Focusing on innovation without discussing access is disingenuous. We risk alienating ourselves precisely when we have so much to contribute to the political and social debate. It is no coincidence that many polls rank the pharmaceutical industry as less trusted than the tobacco industry. We need to change the debate about biopharmaceutical innovation from a political football to a reasoned dialogue about two driving truths: one, as a society we possess an incessant drive for innovation leading to novel treatments based on emerging biological insights; and, two, we possess a deep desire for expanding access to medical treatments to all who need them. We need to separate the innovation issue from the access issue. By way of an example, as a society we don't ask our legislature to control the price of food; but as a society we ensure that anyone whose income is below the poverty line receives access through food stamps or other welfare services. It is time to seize the initiative and to be part of the solution on biopharmaceuticals. History shows that high-risk innovation is best conducted in the private sector and that the government is not good at choosing winners and losers in any industry. The biopharmaceutical industry should be leading the debate on the hard choices needed to ensure access to medicines in the developed and developing world.

What's Your Opinion?

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Reputation management

Our reputation is hanging by a thread. And because reputation has significant impact on a company's revenue, physician/advocacy relationships, and government regulations, reputation management will become a priority for many companies in 2005.

We need only look at the pain Merck is experiencing, as groups focus their intense scrutiny on Vioxx. With legal costs estimated between $4 billion and $18 billion, how long will it be before consumers and analysts begin to trust Merck products again?

For years, it seemed that our industry could do no wrong. After all, we develop innovative medicines that enable people to live longer and more productive lives. We can list antiretrovirals for treating HIV and imatinib mesylate for treating leukemia as examples of our contributions to society.

But our industry can no longer rest on its laurels. In the last five to six years, the industry's reputation began its spiral trend downward. It's only recently that we began to focus our attention to the problem. And now that we know reputation management will be one of the challenges companies face in 2005, the question becomes, "will executives dedicate their resources and corporate strategy to address the issue?"

Reputation management should be integrated in customer service, brand marketing, corporate-strategic planning, sales, and yes, even R&D. Everything a company does should link back to its reputation. Time will tell before we know how many pharmaceutical companies leaders will embark on a reputation-management strategy.

Marita Gomez
PARTNER
HEALTHINFO DIRECT

CHAMBERLAIN. When Nexium feels like Nike and Claritin mimics Clairol, as one prominent newspaper has observed, it's easy to misinterpret the industry's mission and its motive. During the past five years, as the volume of medication messages directed at consumers has risen dramatically, a harsh and, some would say, partisan critique of the industry has emerged. Reducing the public animus and maintaining a patient focus are now two of the most important challenges facing the industry. A recent CBS News poll indicates the depth to which the industry's reputation has sunk — only 15% of Americans have a positive impression of drug companies. This decline is stunning in its implications. The more popular or prolific a brand becomes, the more likely it is to encounter criticism and controversy. This unintended consequence of consumer marketing now weighs heavily on the whole industry. Industry insiders — those reading this publication and their constituencies — characterize the criticism as unfair, although not completely unfounded. Modifications to some promotional practices seem appropriate but won't dampen the cynicism or reduce the industry's vulnerability. Nor can these modifications presume to alter the nature of competition in a free-enterprise system. Industry can take several steps right now to reduce the animosity. It can share credit with its partners in universities and government. It can rely more on science and less on emotion in consumer advertisements. Brand managers must have their antenna tuned not solely to their target audience but to the wider world if they are to maintain brand equity and corporate goodwill. Companies also can assess and act on clinical risks earlier. This could go a long way to reducing the impact of negative news. And industry should never mistake significant medical findings for a marketing threat. Instead, companies should mobilize around competitive advantages that truly exist and above all else create an enduring, positive agenda that emphasizes the patient. Critics are doing an excellent job of influencing public opinion. By taking two relatively small steps the industry can help humanize itself and reclaim considerable ground.

S. LEVY. Between rising healthcare costs across the board, a somewhat disingenuous political discussion about importation of drugs from Canada, and scandals, such as the suicidal threat in kids on Paxil, improved public relations would be useful in 2005. In 2005, the pharmaceutical industry will have to place a continued spin on its self-image through the expanded inclusion of celebrity and patient spokespeople testimonials highlighting the many benefits associated with the continued research available through pharma's current drug-to-market model. In Europe, where healthcare is a state function, pharma companies do not have the same reputation as "profit-driven companies with little regard for average people who bear the weight of high drug prices." European pharma companies are viewed more as scientific pioneers without which healthcare would be less effective.

W. LEVY. Companies must explain to shareholders and the public more effectively that local economic conditions will dictate the pricing of products, that the high cost of drug development must be borne by the small fraction of drugs that reach the market, and that the cost of prescription drugs represents a very small component of total healthcare costs. The public should be focused on lowering the cost of healthcare, not only drugs, and the greatest concern should be directed toward the largest contributors to that total cost.

KERMANI. Every government is concerned about the rising costs of healthcare and in meeting the demand. The uncertain economic situation combined with a growing elderly population and falling birth rates places a great strain on funding public healthcare. The Organization for Economic Cooperation and Development (OECD) has estimated that in the 1970s the average healthcare expenditure share of gross domestic product (GDP) was around 5%; it is now closer to 9%. Governments will therefore look for means to slow expenditure, and it is likely that they will further target the pharmaceutical industry. The pharmaceutical industry is going to have to respond and show that, far from being a problem, greater expenditure on pharmaceuticals is an important part of the delivery of high-quality healthcare. When used effectively and appropriately, drugs are cost-effective healthcare solutions since they can remove the need for expensive, lengthy stays in the hospital. Furthermore, some of the new drugs actually aim to modify the course of the disease, thus improving the quality of life for patients. The rising cost of drugs needs to be placed in the context of healthcare in general; downward pressure on prices will not miraculously make healthcare affordable. The Centers for Medicare and Medicaid Services (CMS) found that pharmaceuticals accounted for only 9.4% of the total $1.3 trillion spent on U.S. healthcare in 2000. Although there will be continued pressure on pharmaceutical companies to justify their prices in line with social objectives, other nonpharmaceutical elements involved in healthcare expenditure need to be tackled. From a more global perspective, as a society we need to make further progress in develop-

Pharmaceutical and biotechnology companies need to better communicate the benefits of their products, not just in terms of efficacy but as part of an overall economic value proposition. For instance, the industry has to find a way to put a dollar value on how new therapies can reduce the need for hospitalization.

DR. BEH SWAN GIN
Singapore Economic Development Board

ing drugs for diseases that primarily affect developing countries. There is often negative coverage of the pharmaceutical industry in the media when it comes to this issue, but there are a lot of people in the industry who do wish to see their companies play a more proactive and benevolent role and we are beginning to see the results of their efforts. Recently, for example, AstraZeneca opened a dedicated research facility in Bangalore, India, focusing on tuberculosis and Novartis opened its Institute for Tropical Diseases in Singapore. Although the industry must make more effort, it would be unfair for the media not to recognize these as steps forward. Simply providing free or affordable drugs is not the answer to tackling these diseases; time and money must be invested in developing collaborations with international, governmental, and local agencies so that a long-term benefit can be achieved. Similarly, the industry must also work with healthcare agencies in industrialized countries to ensure equal healthcare for all.

STERN. Pharmaceutical companies are under constant attack. During the elections of 2004, healthcare was a major focus of both candidates. Drug pricing and importation from Canada remain significant challenges for our industry. As pharmaceutical manufacturers, we need to show our customers the value that we bring to healthcare. We have not done a good enough job to differentiate our brands from generics or to show the benefits of using branded pharmaceuticals to consumers, patients, and healthcare providers. The industry continues to bring new drugs to the market that save lives (and are quite expensive to develop). In addition to the drugs, we are developing valuable programs to help patients adhere to medication regimens. I believe that 2005 will be a critical year for the industry to show the value that we add to society.

LOVE. There will continue to be intense healthcare system cost pressures in Europe, Japan, and the United States. The industry will need to engage its critics, payers, healthcare professionals, and consumers more effectively by explaining its real value proposition — treating diseases cost-effectively.

NASH-WONG. Among the greatest challenges is obtaining product differentiation, which can be next to impossible when therapeutic classes are flooded with me-too drugs, extended-release formulations, and generic options. Those companies that are successful at differentiating their products from the pack often suffer a backlash from managed-care groups that tighten formulary access and add prior authorization restrictions. To further exacerbate the situation, pharma faces a massive, uphill public-relations battle. With drug prices rising faster than inflation and the Medicare drug benefit focusing attention on the senior citizens who can't afford to pay for their prescriptions, importation has and will continue to be a hot topic in the year ahead. Therefore, for manufacturers to succeed in a hostile environment, the key is to have a strong value proposition for all stakeholders: prescribers, payers, and patients.

TILLETT. The No. 1 issue facing the biotech industry is how to separate itself from big pharma in the eyes of the public-equity markets. While big pharma companies are our partners in healthcare, smaller biotechnology companies need to find a way to separate the issues of big pharma from the value that biotech companies are creating with innovative new products. If we have a repeat of 1993,

KRISTINE NASH-WONG
HealthMedia Inc.

For manufacturers to succeed in a hostile environment, the key is to have a strong value proposition for all stakeholders: prescribers, payers, and patients.

we will all have serious problems. The challenge is to present a message of innovation that will be rewarded regardless of government policy effects on the shorter-term problems facing big pharma.

TURETT. The growing skepticism among the public and press of all major institutions creates a more complicated environment for communications firms representing multinational corporations. Add to that the critical environment in which the pharmaceutical industry now finds itself, and there is what an optimistic PR person can only call a wonderful challenge. That being said, brands, companies, and representatives who conduct themselves with integrity and transparency still will be able to market their products effectively.

BOILY. The industry has seen an escalation in lawsuits by state attorneys general, federal prosecutors, and whistle-blowers. Pharmaceutical companies are facing a growing chorus demanding that they revamp their sales and marketing practices. Major initiatives have taken place because of the implementation of the PhRMA Code on Interactions with Healthcare Professionals and the 2003 Office of the Inspector General Compliance Program for Pharmaceutical Manufacturers. All agree that scrutiny will increase in 2006 when the new Medicare drug plan takes full effect. It has

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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-