What's Your Opinion?

2005 — A LOOK AHEAD

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

Pricing — a mob mentality

2005 may very well be the year of pricing. There's a mob mentality regarding U.S./international price differences, importation, and the "no price negotiation" clause in the Medicare prescription drug benefit.

Pricing is the way life-sciences companies capture the value they work so hard to produce. Their success, and ultimate survival, will depend on their pricing ability.

Pricing won't get any easier in 2005. Healthcare providers and public/private insurers are rolling out new and creative ways to get companies to start price wars. Others will use the media and public outcry to try to force pricing concessions.

Companies that are best able to get stakeholders to believe in the value of their products and to understand the value-price connection will be least likely to fall victim to the angry mob.

David Webster
President
The Webster Consulting Group Inc.

in a timely fashion. There is a need to reconcile development and regulatory more closely with the opportunity and let some of these nonbillion-dollar products get to the market.

LOVE. Without a doubt we have our work cut out for us in sustaining product flow by developing truly innovative compounds for unmet medical needs. Everyone — from analysts to doctors to patients to payers — wants innovative products, but the systemic cost pressures are coming at a time of increasing research, development, and regulatory complexity.

TILLETT. The reality of innovation is that it is inversely proportional to company size. It is extremely difficult for even the best large company to create, nurture, and maintain an environment of innovation. Innovation by its nature is risky and large companies don't like taking risks. Smaller organizations (for a variety of reasons) are more willing to take those risks and go for the big prize. The other problem is the "blockbuster" model. It means that too many innovative new ideas are left behind because they don't fit the model.

SAVELLO. For new product innovation opportunities, the industry must look to therapeutic areas where there are medical needs such as neurology, cancer, inflammatory diseases, and metabolic diseases. These diseases are pathologically very complex and of varying and complex etiology. The advent of genomics is perhaps one of the more important tools in discovering this new generation of drugs to treat these very difficult diseases. But, it is still early and the full benefit of this technology has yet to be realized. Understanding disease complexity at the molecular level is the only hope we have to discover new medical interventions to alter these disease processes.

S. LEVY. A longer-term trend that hints at the end of blockbusters is the rise of personalized medicine. Many physicians, researchers, and regulators envision a bright future in a pharmaceutical industry where there are fewer one-size-fits-all medicines and many one-size-fits-one therapies. Pharmacogenomics promises to help this evolution. One way of achieving personalization is to identify the genotypes in common with super-responders, regular responders, nonresponders, and those patients who are likely to have increased side effects from a drug. This will improve care and reduce medical errors by identifying which drug will be right for each patient. The problem is that fragmenting the market may not work with the blockbuster model as it is today. As the progress of pharmacogenomics is gradual, the industry will be forced to change.

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NANCY TURETT

Edelman

The nexus of healthcare and technology is where some of the most exciting and important R&D advances are happening. Terms such as healthcare and technology are just convenient ways to classify businesses. By shedding traditional definitions, we'll see that the future is where these fields intermingle.

Those companies that are proactive about personalized medicine will lead.

INTELLECTUAL PROPERTY

SHANAHAN. The ability to codify and share intellectual property (i.e., scientific understanding) can bring the 20% R&D cost closer to 16% to 18% of revenue. The current inability to codify and share is at the root of the following challenges: bringing new drugs and therapies to market in an increasingly regulated environment; accelerating the understanding of gene-based and protein-based interactions in cells, upon which new drug discovery depends; effectively managing research where collaboration between departments and across companies is prevalent; and lowering the marginal cost of drug-discovery research and development. Current codification of intellectual prop-

DR. DAVID SAVELLO
Cardinal Health Inc.

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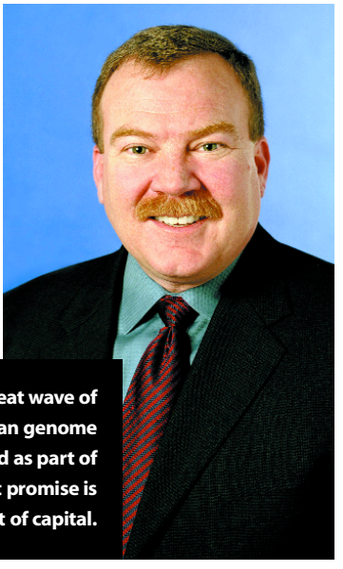
STEVEN LEVY
Fletcher/CSI

DR. DONALD DRAKEMAN
Medarex Inc.

Much of the innovation in pharmaceutical development now resides in the biotech sector, and the challenge is to find the most efficient and productive ways to combine biotech's innovation with the industry's strength in research, development, and marketing.

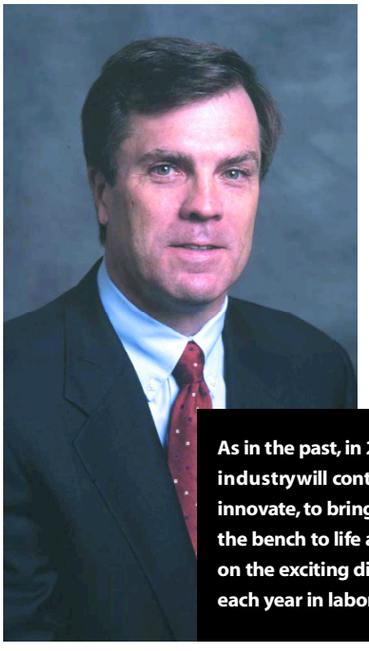
DR. THOMAS WICKS
Odyssey Pharmaceuticals Inc.

The industry must address how to continue treatment innovation while limiting costs. One solution to the situation is to increase collaboration among international companies.



MICHAEL BONNEY
Cubist Pharmaceuticals Inc.

We are on the cusp of the next great wave of innovation. The mapping of the human genome and the tools that have been developed as part of that effort hold great promise. But that promise is threatened by an increasing cost of capital.



BRUCE PEACOCK
Adolor Corp.

As in the past, in 2005 and beyond, our industry will continue to be challenged to innovate, to bring the ideas developed at the bench to life as medicine, and to deliver on the exciting discoveries taking place each year in laboratories across the globe.

erty in ad-hoc office documents or programming languages is slowing the pace at which IP can be shared, reused, and collaborated on.

SAVELLO. Patents and intellectual property are under attack all over the world. Even though only three of 10 new drugs approved earn enough money to pay for their development, governments, patient-advocacy groups, and generic drug companies are constantly on the attack to weaken the intellectual property cornerstone of innovation.

MATTHEWS. Counterfeiting and the growing international effort to undermine patents are big challenges. There is growing evidence that counterfeiting is exploding around the world, especially in developing countries. Some counterfeiters are so sophisticated that they can virtually duplicate elaborate packaging, even while they pay little or no attention

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Website ROI

From an e-marketing perspective, 2005 will be a year of increased accountability for program performance. Challenged by the indirect sales environment, marketers will need to find new ways to measure the impact of their Websites and e-promotions on prescriptions and sales.

To improve Web performance there should be an increased focus on driving information seekers, especially consumers, to a measurable call-to-action.

Marketers need to look to new tools, such as intelligent search engines, that can deliver more personalized, contextual content based on visitors' intent. Important side benefits of any optimization will be improved customer service that will help build trust, or rebuild it, in a time of poor public image.

Marketers will continue to find it harder to reach and influence healthcare providers so expect an increase in Web-based initiatives, where users favor learning in their own time in an environment they can control.

As the Web becomes increasingly important to professionals and consumers alike, successful marketers will integrate Web programs across all marketing channels, instead of treating them as discrete, nontraditional communication channels.

Ian Cross
CEO
I-SITE

to the drug inside. The problem is that the industry and the FDA are doing everything they can to stop the counterfeiting and getting no credit for it, indeed, they are being criticized by politicians and others for their attempts. But, if — and most likely when — Americans are hurt by counterfeit drugs, those same politicians will blame the industry for not doing enough. The international attempt to undermine patent rights comes in at a close second to counterfeiting. The industry, however, has taken some very positive steps. Partnering with countries that want to attract R&D industries, as some have done, is exactly the right move. Licensing out generics to other companies overseas is also good. Both actions attempt to bring countries in and make allies of them rather than adversaries. And, if these efforts work, in the long run those countries will enjoy strong economic growth, which will encourage them to strengthen patent protections even more.

BEH SWAN GIN. Intellectual property protection is the lifeblood of this industry. A growing issue for many biomedical companies is the need to ensure that their IP is protected even as the industry explores opportunities for outsourcing to cheaper locations, locations where the regulatory framework for IP protection is still evolving. We believe that Singapore offers one of the best places in Asia for the commercialization of ideas and innovations because it boasts the strongest IP protection regime in the region. For instance, Singapore was ranked as the most IP-protective country in Asia in 2003 by PERC, the Political and Economic Risk Consultancy Ltd. In 2002, the World Economic Forum and the Institute for Management Development also ranked Singapore top in Asia for IP protection. Singapore is a member of all of the key IP-related conventions and organizations such as the Paris Convention, Berne Convention, Madrid Protocol, Patent Cooperation Treaty, Budapest Treaty, Agreement on Trade-related aspects of IP rights, and World Intellectual Property Organization. The IP chapter of the US-Singapore Free Trade Agreement (USSFTA) also brought Singapore's IP regulations in line with U.S. practices.

▶ MARKETING/PROMOTION

STERN. The great thing about marketing today is that we have more methods to choose from to get our messages out to our customers: patients and healthcare providers. As marketers, though, the challenge is to use the methods in ways that the strengths can be advantageous. It seems clear now that DTC advertising on TV is not as powerful as it was when it first appeared in 1997. Today, fewer physicians are willing to prescribe the drug that patients ask for, simply because they have seen a commercial on TV. The power of DTC TV advertising is that it has created much higher disease awareness, and it can be used to deliver compliance and adherence messages. The Internet can be a very powerful tool, but too many marketers are still using it to deliver static messages to patients and healthcare providers. The beauty of the Internet is the ability to use its interactive properties to create better and stronger relationships with people.

SAUNDERS. We have adopted the PhRMA code as a company but we also have supplemented the PhRMA code with our own internal additional requirements. And we're building the processes and support mechanisms throughout the company to ensure our compliance with these standards. With regard to GCP, we're looking at ensuring that we have the right internal controls in place to comply with the good clinical practices throughout the world.

ROSENBERG. The largest challenges will be around how products are marketed, especially products that fall under the specialty diseases category, such as psychotropic drugs or products used to treat moderate-to-severe pain. The FDA will be scrutinizing heavily the use of clinical reprints and articles used to support product claims. The days when companies could push the envelope and use animal studies, patient-case studies, or open-label studies to support product claims are gone. The FDA will be looking for well-controlled clinical studies to support any marketing claims made to healthcare providers. This more closely matches what has been done from a regulatory standpoint in Europe and Japan for several years.

SHANAHAN. More and more companies will need to distribute not just scientific papers and brochures to doctors but actual systems biology models that describe therapies and enable the doctor to have a deeper understanding of the products they are considering. Without these interactive tools for instruction and guidance for products, which can be highly regulated, little will change in drug promotion.

R.LEVY. Gaining access to the target audience is, and will continue to be, our biggest challenge. With the increased competition and noise, gaining access is tougher — and more critical — than ever. Smart marketers have to use every tool in their toolbox to find ways to be in the right place at the right time. We have to use every avenue available — both direct and indirect — to make sure we are