What's Your Opinion?

2005 — A LOOK AHEAD

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

A sense of entitlement

The most significant business challenge the pharma industry will face in 2005 is the sense of entitlement among patients in its largest market, the United States. Social pressures resistant to the productivity of our industry continue to build like storm clouds before a hurricane. The underlying problem, in my mind, is that consumers of healthcare have come to expect the highest quality of care without a need to pay for that superior care.

Can you imagine any politician taking a stand for a group of citizens demanding a BMW at the price of a Chevy? Yet, in this last election many politicians made attacks upon the price of pharmaceuticals a plank in their reelection platforms.

Consumers of healthcare must come to realize that our industry, to be productive, focuses upon improving the quality of the products available to keep us well. If those products work better than less costly alternatives, it is only right and natural that they cost more.

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from CROs, pharmaceutical companies, publishers, and agencies to healthcare professionals and consumers. Sadly, this is not a winning prescription for anyone, most of all the people who would benefit the most — patients who need new treatments for painful and life-threatening conditions.

B. THOMPSON. Probably the most significant challenge is the increasing, and somewhat unreasonable, pressure for price controls on new pharmaceuticals. The industry as a whole is nearing the end of patent protection for brand-name products representing tens of billions of dollars in sales. Inevitably, this will cause, and already is causing, tremendous pressure on the price of brand-name pharmaceuticals.

TILLETT. The impact of the fallout concerning either government-imposed price controls or importing of patented drugs from outside the United States has the potential to cause a significant flight of capital out of the healthcare markets. This would have negative consequences to both public and private biotech companies, which are dependent upon the equity markets to fund clinical development of new products.

KERMANI. I think that the pharmaceutical industry will face the same political, regulatory, social, and economic challenges that it has experienced in the last few years, but the pressure to deal with these issues will intensify if companies are to continue to operate successfully. There has definitely been a tremendous change in attitudes among consumers and politicians in the last five years. In the United States, we now hear people expressing views about parallel importation from Canada to reduce drug prices. A few years ago, this issue certainly did not receive the coverage it does now. Parallel importation has actually been occurring in Europe for a number of years, but only now are those in favor of such moves in the United Sates suddenly referring to it. Basically, there is greater scrutiny of pharmaceutical pricing all around the world. No market can be taken for granted, even emerging ones in Asia, Latin America, and Africa. Governments are reacting to public pressure by implementing, or at least examining, policies that will have a downward pressure on prices. In Europe and Japan this is very direct, with governments running a variety of pricing systems to set prices. In the United States, although there are no direct pricing systems in the European and Japanese sense, many politicians have been suggesting ideas such as parallel importation from Canada and the media has given greater air time to such views.

TILLETT. Managing country-by-country pricing is a major issue. Secondly, we need to begin moving toward a more holistic view of the healthcare market so that we are not just selling products to the doctor, but that we involve all affected parties — patients, payers, CMS, employers, and so on, to create a service business that provides improved healthcare at an affordable cost.

BUA. The industry will face significant drug pricing pressure that could have a depressing impact on product innovation. Over the past five years, new drug approvals have been comprised primarily of line extensions lacking significant innovation as well as other me-too type products. Few truly innovative NDAs have been filed and approved. Sadly, over the long term, this is a negative for innovation. Formularies and insurers already are pressuring drug manufacturers for deeper discounts, and states are exploring (some already approving) ex-U.S. prescription drug purchase programs. This type of pricing pressure will lead to future price sensitivity and potentially will affect significantly the amount of time and money pharmaceutical companies are willing to invest in high-risk but potentially life-saving innovative new therapies.

ROSENBERG. Pricing and contracting with large GPO buying groups and wholesale distributors will be one of the greatest challenges companies will face. As wholesalers move toward a more fee-for-service structure to help their profit margins, pharmaceutical companies will have to create different types of contracts that will likely be less lucrative than what they have had in the past.

▶ INNOVATION

DRAKEMAN. The engine that drives growth in the pharmaceutical industry is the discovery of new medicines for unmet medical needs. Much of the innovation in development now resides in the biotech sector. The challenge is to find the most efficient and productive ways to combine biotech's innovation with the pharmaceutical industry's strengths in research, development, and marketing.

SCOZZIE. Some of the best new innovations are coming from the young companies. Perhaps big pharma should take a closer look at the innovation/entrepreneurial approaches of some of these companies to extract learnings. Another issue is the need for "big winners." This means a lot of smaller product opportunities, which could become big, either aren't being pursued at all or are not being pursued

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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-