What's Your Opinion?

2005 — A LOOK AHEAD

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

Drug safety

The major business challenge facing the pharmaceutical industry will be drug safety. Proving drug safety, and then monitoring it more transparently, will cost pharma companies. Sarbanes-Oxley is an apt simile for what pharma companies may face.

Dodge Bingham
VP, Strategy and Development
Thomson Healthcare — PDR

Multiple challenges

In 2005, the pharmaceutical industry will need to contend with several challenges: drug-safety issues, poor management, pricing issues/government control, innovation, and the emergence and impact of consumer-directed healthcare.

Dr. Stephen Schectman

Clinical-trial barriers

We see clinical-trial process barriers — both internal (pharma decision models, timetables, and expertise) and external (media coverage, site resource challenges, competitive trials, and narrow subject population targets) — as continuing to adversely impact study-completion timelines in 2005.

Frank S. Kilpatrick
President
Healthcare Communications Group

costs. One solution to the situation is increased collaboration among international companies. By sharing the responsibilities and investments required for new drug development, companies can limit their liabilities, while positioning themselves to receive financial rewards.

MCNAMARA. There are a number of global healthcare issues that will affect the industry in 2005, from how we can better address issues of access — to physicians, medications, and quality care — in developing countries to how we can better combat bioterrorism. But one of the most significant issues we face in the coming year is how we can build better clinical-development programs. The need for good medications and new therapies for diseases is universal, yet there is a lack of international standards of care and clinical development. Setting these standards and making it easier for pharmaceutical companies to operate clinical programs more seamlessly around the world will benefit all. Of course, part of the process of setting international standards and including more nations in clinical development involves the pharmaceutical industry working more diligently to explore opportunities in countries such as China, India, and Russia and finding ways to work effectively in those markets.

ZELDIS. The European medical research regulations have changed dramatically and will require effective implementation at the local level. Japan's practices for obtaining regulatory approvals are in evolution. Price differentials may result in single pricing structures for drugs internationally. The industry will have to work with the World Health Organization (WHO) and other organizations to deal with patent issues, as well as the cost of drugs in countries that cannot afford the price of meaningful therapeutics.

HURLEY. Because of its excellent enrollment and retention rates, Latin America is growing in popularity as a region of choice for clinical trials to supplement the United States and Western Europe. With a patient population of more than 500 million people across a broad spectrum of disease areas, Latin America offers valuable alternatives that help expedite clinical-development timelines through seasonal advantages and fewer competing studies. Other advantages to conducting clinical trials in Latin America include: quality per FDA inspection results on par with Western Europe; excellent enrollment rates per site averaging two to four times that of the United States and Western Europe; established regulatory systems that reflect ICH-GCP standards with competitive timelines for approvals; and significant patient populations for type 2 diabetes and oncology trials. In addition, according to a recent study cited in *The Wall Street Journal* and conducted by Chicago-based Jones Lang LaSalle Inc., Latin America comes out ahead of other areas around the globe as an offshore market when factors such as labor quality, labor supply, and time-zone differences are taken into account. Latin America will only continue to grow in importance as a key region for the development of new medicines as biopharmaceutical companies continue to discover and experience these significant advantages.

▶ IMPORTATION/PRICE CONTROLS

NASH-WONG. Pharmaceutical price differential in the international markets will be top of mind. So extreme it's been called a trade deficit; the U.S. market is currently carrying the cost of R&D for the world. This price differential is just adding fuel to the pharma PR fire. How can we successfully argue the value of pharmaceuticals here at home when our neighbors to the north and European markets are getting the same product at a fraction of the cost that U.S. consumers are paying? Through mandated prices, limited access, and Rx-to-OTC switches, the international market has successfully limited the pharmaceutical industry and created the drive for importation.

BIAGGI. One of the most significant challenges is the impact of drug imports from Canada on market prices and how the industry will deal with the growing political support for easing restrictions. It would be good to see government leaders request that Canada level the field by allowing U.S. products to be marketed freely in Canada. This would open the Canadian market to many small- and medium-sized U.S.-based pharmaceutical companies.

CAMPBELL. Importation will come to the forefront in 2005. At this point, there are clearly more questions than answers for the pharmaceutical industry. If importation is allowed in some manner, how will it affect drug companies, consumers, and distributors? Also, depending upon the impact of importation, will the U.S. government take corrective measures to offset the influx of imported drugs? Will the government leverage its buying power when dealing with other nations and the pharmaceutical industry in general? What will be the pharmaceutical industry's strategy to capture market share and how will a drop in the cost of current drugs affect the industry's ability to fund research and devel-

opment for future products? For many reasons the debate surrounding importation will shape the pharmaceutical industry in 2005.

ERICKSON. Any major impact on pricing of proprietary drugs, through importation from highly regulated, low-price countries, significant cuts in reimbursement, or attempts at direct or indirect price controls will force companies to pursue changes in strategy that will dwarf the changes experienced in the early 1990s. Depending on the specific issues, one outcome may be that pharmaceutical and biotechnology companies pursue a U.S.-only strategy for truly differentiated products to maintain pricing and margins.

HAMELIN. There likely will be greater government involvement in price controls and/or negotiations on U.S. pharmaceutical pricing, which will cause a restructuring of the industry and a loss of working capital.

KARCZEWSKI. The biggest issues facing pharmaceutical marketers today are government intervention, imports, and rising prices. It's becoming more and more difficult to work efficiently, as the government reconfigures new rules and regulations that are often hazy at best. Budgets are being squeezed tighter and tighter as companies contend with increased regulations, imports from abroad, and rising healthcare costs, all of which are putting pressure on companies to raise their

THE RATIONALE FOR COMBINING HEALTH ECONOMICS AND STRATEGIC REIMBURSEMENT PLANNING

The increasingly cost-conscious nature of formulary decisions and the willingness of payers to reject a drug for listing based on budget impact reasoning means that pharmaceutical manufacturers must address the issue of affordability at an early stage in the drug-development process.

If correctly applied, health economics techniques will deliver a product unit price that creates a win-win situation between the manufacturer and the purchaser or prescriber of the drug, thus ensuring early product reimbursement, rapid product uptake, and maximum market share.

Reimbursement for a new treatment must reflect its value and be easy to obtain if it is to experience rapid uptake in the marketplace. Studies of a drug's value should always include an understanding of who will pay for the drug or treatment, if the reimbursement will be appropriate and affordable, and what barriers to access will the provider and payer experience.

A first step can be to understand how payers are evaluating the applicable therapeutic class, including those aspects of the reimbursement environment that will or could affect how the class is evaluated, and how payers distinguish it among the members of the class. This early qualitative market research with payer stakeholders, such as medical and pharmacy directors, can help companies understand whether the potential value story will be sufficient to distinguish a product from competitors or whether, if the clinical profile is the same, price will be the most significant factor.

It is important to hear the bad news about reimbursement early so that a manufacturer has time to build a strategy to eliminate or mitigate the problem. A well-planned economic analysis that includes reimbursement should also help companies uncover and eliminate or control any expected barriers to access.

Closely thereafter, it is important to think about the fine points on how the drug or technology will be reimbursed. This should be done at about the same time that the product's economic profile is built. Adequate attention to how the product will be reimbursed compared with competitors will help executives understand the issues that they must be prepared to overcome.

A product launch always requires a detailed launch to payers, which would include how the economic value message will be delivered to the payer audiences and by whom. Finally, reimbursement pull-through at the provider level is essential to ensure that the provider will be sufficiently reimbursed to make it worthwhile to offer the treatment.

It is evident, based on this year's changes in the Centers for Medicare and Medicaid Services (CMS) direction and policies as a result of the 2003 Medicare Modernization Act, that data generated from clinical and economic studies will be pivotal in determining coverage and reimbursement policies. CMS is moving toward evidence-based reimbursement.

COMPONENTS OF A HEALTH ECONOMIC STRATEGY AND REIMBURSEMENT ASSESSMENT

PAYER MIX analysis for disease and population;
PROJECTED COSTS of treating the disease;
PROJECTION OF REIMBURSEMENT environment based on payer rules and site of care;
DETERMINATION OF PRODUCT VALUE based on economic modeling or other health economic studies;
PLANS FOR THE LAUNCH TO PAYERS, including how the product's value will be demonstrated; and
REIMBURSEMENT-SUPPORT PROGRAMS for field force and providers.

Source: Laurie G. Hughes, MBA, Executive Director, MEDTAP International – Center for Pricing & Reimbursement, Arlington, Va. For more information, visit pharmanalysisgroup.com. L. Clark Paramore, MSPH, Deputy Director, MEDTAP International — Center for Health Economics and Policy, Bethesda, Md. For more information, visit medtap.com.

What's Your Opinion?

2005 — A LOOK AHEAD

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

Justifying prices and regulatory scrutiny

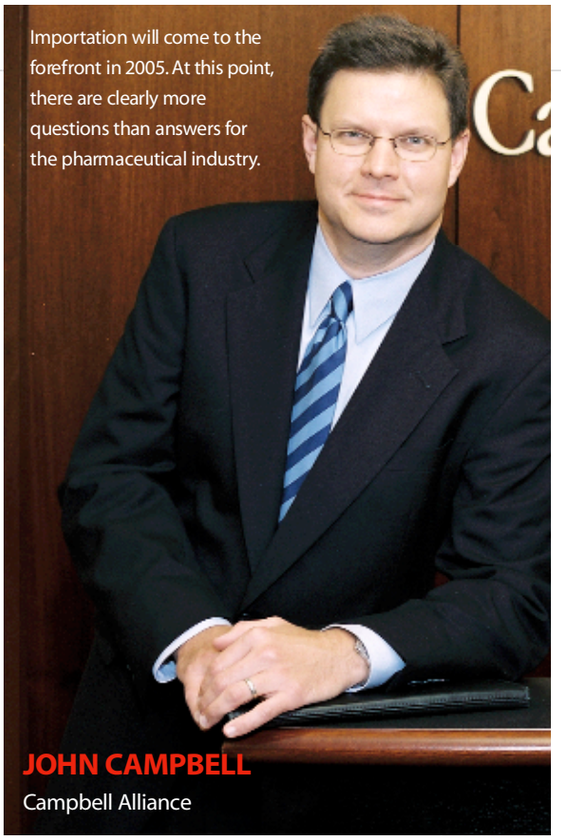
Going into 2005, this industry will be faced with two major challenges. Pharmaceutical companies will continue to feel pressure to justify price and demonstrate access to affordable medication. At the same time, increased scrutiny from the FDA stemming from the recent Vioxx recall will require pharma companies and their agencies to not only demonstrate the safety of new products, but also to clearly show the advantages they can provide over existing treatments.

Communications around these issues will continue to be challenging as access to doctors becomes even more limited.

Blane Walter
CHAIRMAN AND CEO
INCHORD COMMUNICATIONS INC.

own prices by double-digit percentages. Price controls may be inevitable, depending on how fast prices accelerate and the nature of the political environment.

R. LEVY. Overall healthcare costs, including the cost of pharmaceuticals, Medicare, and Medicaid are all key issues of concentration. Unfortunately, with an aging population and cost pressures escalating, I believe the government will be forced to put tighter constraints on the industry. As marketers review how government initiatives will affect their margins, they will become very cautious about how and where they spend their dollars. Fears that governmental controls will cut into their profits will push companies to take a more conservative approach to protect their margins, cutting back on expenses, from R&D to marketing. This, in turn, will affect drug pipelines, marketing initiatives, and patients. It's a vicious cycle, which is another challenge in itself. Drug pipelines and launches do not look plentiful for 2005. There's a trickle-down effect that will impact every stakeholder in the field,



Importation will come to the forefront in 2005. At this point, there are clearly more questions than answers for the pharmaceutical industry.

JOHN CAMPBELL
Campbell Alliance

DRUG IMPORTATION MAY RESULT IN HIGHER, NOT LOWER, CONSUMER COSTS

The long-run costs of importation are easily ignored by politicians, such as Illinois Governor Rod Blagojevic, who is granting access to cheaper drugs by expanding Internet purchasing of pharmaceuticals from countries such as Canada and Ireland.

But this search for a quick bargain could prove expensive, as the Governor isn't likely to be in office when future data prove importation harmful. According to a new study by the Institute for Policy Innovation (IPI), importing drugs is not a guarantee for cheaper prices, and in the long run, may result in more expensive drugs and medicine shortages.

Prescription drug importation "amount[s] not so much to consumer or government savings as to increased profits for pharmacists and producers," says Jacob Arfwedson, author of the Parallel Trade in Pharmaceuticals study.

Further evidence against importation is found in Mr. Arfwedson's comparison of the United States and Europe.

SHARE OF R&D. As the United States has stayed off importation, it has gained the lion's share of pharmaceutical research and development (R&D). This is quite a contrast to the 1960s when European countries did most of the R&D. European R&D has decreased to 59% from 73% (1990-1999, percentage of European companies' global R&D expenditure).

SHARE OF WORLD PHARMACEUTICAL MARKET. The United States has increased its share of the world pharmaceutical market from 31% to 43% during the past decade. In contrast, as Europe has allowed more importation, its share in the world pharmaceutical market has declined to 22% from 32%.

Source: Institute for Policy Innovation, Washington, D.C. For more information, visit ipi.org.

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.

Jay Carter
SENIOR VP, DIRECTOR OF CLIENT SERVICES
ABELSON-TAYLOR INC.

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