What's Your Opinion?

2005 — A LOOK AHEAD

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

Medical education

As an owner of an organization involved in education in the pharmaceutical industry, I believe that one the most significant business challenges in 2005 will be creating the level of educational programs required for medical professionals given the current regulatory climate. Misinterpretation of guidelines and an overriding fear of potential consequences are causing key physician educators to be removed from the learning process. Therefore, the necessary knowledge transfer is less effective. As an industry that depends on the creation and propagation of high-level clinical information, we need to come to grips with the regulations and apply them in a manner that fosters a meaningful educational environment.

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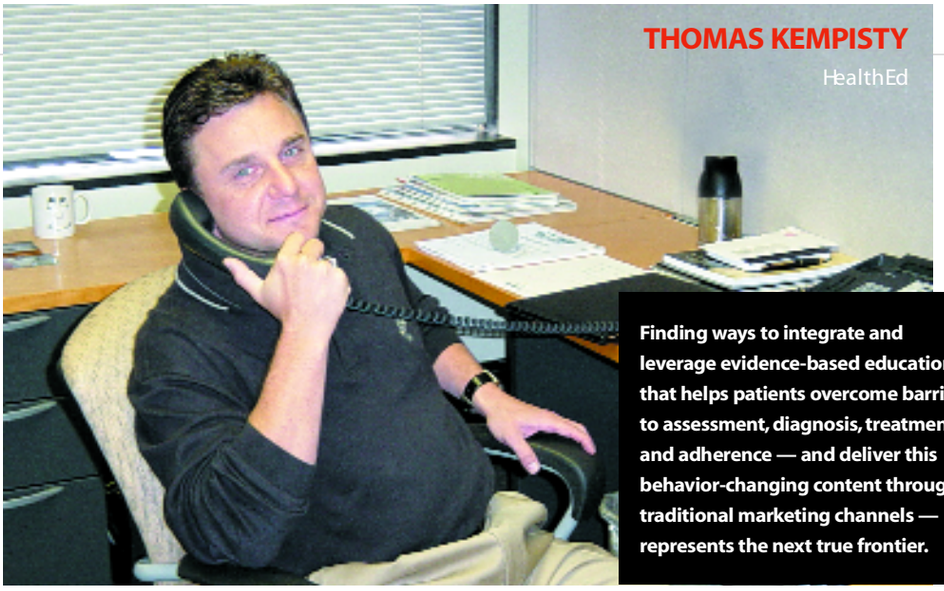

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Finding ways to integrate and leverage evidence-based education that helps patients overcome barriers to assessment, diagnosis, treatment, and adherence — and deliver this behavior-changing content through traditional marketing channels — represents the next true frontier.

now relates to the entire field of publishing clinical-trial results. Historically, the industry has tried to do a good job of getting results published in leading journals that undergo a peer-review process, which is very healthy for the publications. Unfortunately, many of the best journals do not like to publish clinical-trial studies and results so companies end up publishing results in lesser read, not necessarily peer-reviewed journals. I find it very interesting that publications have been pushing for all clinical trials to be published in the best, peer-reviewed journals, but in my experience these same publications are rejecting many studies that are submitted. The whole arena of medical publications will be an interesting and controversial area in the coming years. This will have a huge impact, causing changes in marketing practices across the industry.

MEDICARE

CAMPBELL. Executives will continue to prepare for the new regulations approved under the Medicare Prescription Drug, Improvement and Modernization Act (MMA). These regulations will take effect as scheduled on Jan. 1, 2006. Before the full benefit's official start, however, the industry faces far more imminent deadlines, which could have a significant impact on the way it does business. For example, pricing and contracting strategies must be developed by the end of first-quarter 2005, and they will have a significant impact on drug reimbursement for years to come.

BARNETT. With more than 40 million current Medicare beneficiaries in the United States, the stakes are high for pharmaceutical companies, and the window for making strategic decisions is small. Choices that pharma companies make in the next 14 months are likely to have far-reaching effects on long-term performance, so companies must take extreme care to avoid costly mistakes.

BOILY. MMA has drawn close scrutiny by legislators at all levels of government because of the projected costs of providing prescription drugs to the elderly. The Medicare Act will be beneficial in increasing demand for pharmaceutical products. What is far less clear is the extent of the gains for the industry in the wake of off-setting pricing competition and the final number of drug classes that will be included.

PEACOCK. Most people in our industry agree that the next 10 years will bring changes to the Medicare and prescription drug coverage system in this country. While it's impossible to predict what shape these changes will take, we can predict that it is only through a close working relationship with the government that we can develop a system that works for all stakeholders, one that continues to drive innovation while also providing help for those who need it.

HAMELIN. On the one hand MMA is going to potentially increase the number of prescriptions as more and more consumers become able to access affordable medications through Medicare, a positive for the industry. But, on the other hand, as the government helps to defray costs to patients, this will invite more and more government control on prices. This type of regulation could move investors away from investing in pharmaceutical companies, thus lowering the amount of available capital and ultimately leading to further pipeline droughts.

KERMANI. As Europeans we watch closely what happens in the United States as it is the world's biggest pharmaceutical market and

R&D base. For the moment, it does not look as if there will be the dramatic impact on the U.S. industry that has happened as a result of healthcare reforms in certain European countries. In Germany, the government is trying to implement the biggest overhaul of its healthcare system since the 1990s. The government has a long-term healthcare savings target for 2007 amounting to about $25 billion. This has been received very negatively by the pharmaceutical industry and has run into opposition from patients and politicians. Based on the reforms that have been introduced since 1999, the German pharmaceutical industry association estimated that by the end of 2004, sales losses to German industry would reach $3 billion. During 2003, a number of companies in Germany either froze their R&D spending or decreased it. Some even shifted jobs and new investment to other European countries. Other European governments do not want to end up in the same situation as Germany and are talking to the industry about how they can work better together so that reforms do not lead to a decline in the industry's position. For example, the French government launched a high-profile initiative at the beginning of 2004 to study how it could best stimulate the market so that pharmaceutical companies did not reduce investment in the country. So although many in the U.S. industry might be concerned as to how Medicare reform affects the market and R&D environment, from a European perspective the situation looks quite positive.

MULTIFUNCTIONAL TEAMS

WILSON. Historically, the pharmaceutical industry has faced two hurdles: achieving product registration and securing reimbursement. Today, demonstrating product value is becoming a much stronger issue. It's not just a matter of product price, but the impact on total cost of care. The needs of marketing are changing, and it is becoming more essential for the commercial side of the business to communicate more effectively with its R&D colleagues. Marketing must work more closely with R&D to succeed in demonstrating the true value of a company's products. The companies that effectively demonstrate not only the efficacy and safety of their products, but the value of their products, will have a formidable presence in the marketplace.

SULKES. Best practices that we've seen demonstrate deep collaboration by including medical affairs leadership on brand teams with a message from senior management that both medical and marketing leadership must be aligned to move forward on major initiatives. On a brand that recently obtained a heart failure indication, the medical director drove the direction of the messaging with regard to patient types and timing of the diagnosis in a manner that marked a departure from past practices. This approach provided doctors with an entirely new understanding of the role of the treatment category in this disease state.

KRIEGSMAN. Companies need to make the reward system team-oriented so that no single individual is rewarded unless the team succeeds.

ROSENBERG. Marketing departments are always challenged by R&D because there is an unspoken motto within research that simply states, "if you can make another strength, that is the best line extension." But marketing always pushes back with, "just because we can make another strength, doesn't mean the market needs another strength." The key in the future is to have R&D work with marketing to create the appropriate life-cycle management programs for any given product. Further, by working together at all levels, including market research, R&D is likely to take an extra level of ownership for projects pertaining to product life cycles.

PERLOTTO. The best single practice is for the organization to be clearly aligned from the top down. If the leader of an organization is successful in painting the vision for a company and putting the right people in place within R&D, people who understand that the organization is a business based on commercial objectives and commercial success, then that collaboration can take place because both teams have the same objectives in mind. When the mindset within R&D is "research for research sake," the likelihood of successful collaboration is greatly reduced.

KOVAC. One of the most important development concepts used in outside sectors is product life-cycle management (PLM), the management of a product from initial idea through design, launch, and production to marketing and sales. This definition of PLM is foreign to pharma, where the term is used only in a marketing context to describe the management of a drug from the point at which it is launched to the point at which it has generic competition. A pharmaceutical company typically develops a new drug in one country and manufactures it at plants in several other countries. But, the development function rarely consults the manufacturing function to ensure that a formulation is fit for large-scale production. Data related to new drugs should be shared electronically, and manufacturing systems at the different production sites need to be integrated. The sites themselves need to be interchangeable because a drug-manufacturing setup in one country is not automatically validated in another. Any company that wants to develop effective collaboration to streamline or enhance R&D and marketing will need to install an electronic backbone that spans everything from early development to marketing and sales, and one that allows for information to travel in both directions.

NASH-WONG. Collaborative partnerships are imperative in these lean times. R&D and marketing teams working together early in the development life cycle can make a stronger product with defendable attributes and differentiation. Cross-brand collaboration can provide critical opportunities to consolidate similar resources, such as a combined KOL database for hospital products, or a combined unbranded disease-management site. Collaboration shouldn't be restricted just to internal partnerships; stakeholders such as advocacy groups and caregivers shouldn't be ignored.

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