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.

Choices that pharma companies make over 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.

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What's Your Opinion?

2005 — A LOOK AHEAD

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

A drug-benefit plan

One of the biggest trends for the coming year is a drug-benefit plan for Medicare that will take the pressure off of Canadian pharmacy sales to U.S. customers. Another is tort and product liability reform legislation.

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These partnerships can lend independent credibility to manufacturer initiatives and do double duty by influencing the people who impact their brand.

WILHOIT. Collaborations between research and development, sales and marketing, and business operations should be initiated at the very earliest stages of the R&D/commercial life cycle. These collaborations result in highly coordinated development and commercial activities that help optimize both the commercial and technical potential of each product. Furthermore, this approach provides a competitive advantage that is the result of the shared accountability across all functions in the development and commercialization of a company's products and brands. At the core — and a major point of differentiation from most other competitive approaches — should be a consistent collaboration between scientific, medical, and commercial interests from the earliest stages of the product-development process. Starting with basic product attributes, this approach draws together the relevant functional expertise to manage the overall portfolio and develop a shared perspective of each candidate's commercial opportunity and strategic fit. This early and continuous cross-functional collaboration leads to informed decision making, efficient application of resources, integrated medical and marketing plans, and a deep, shared commitment to the overall project objectives from early development to marketing. An explicit commitment from the R&D, sales and marketing, and business operations groups is required to nurture a collaborative environment to realize the maximum potential of each product opportunity. In contrast with more traditional, function-oriented environments, this process offers clear definition of the commercial opportunity as well as alignment of discovery, development, and commercial priorities and goals through early and continuous commercial participation in the research and development process; greater speed to market and to total peak sales through consistent collaboration between functions to prepare both the company and the market for the global launch of key products; expansion of the total product potential by early and sustained focus on product life-cycle management (including pursuit of new indications, dosing strengths, additional formulations, and alternative delivery systems); maximization of the total return on investment through commitment to rigorous intellectual property and patent protection to extend the useful commercial life and create barriers to competitor entry; and joint accountability for product success to maximize commitment and ownership by all participants.

BUA. The recognition that internal company divisions in large pharma can share resources, instead of duplicating them, could enhance collaboration specifically in a large pharma company that has been the product of many mergers of disparate organizations.

ZELDIS. There is a need for cross-functional project teams with supervisory working groups that report to senior managers. These teams should be formed as soon as a development compound is designated as entering an IND track.

KERMANI. Companies have definitely recognized that collaborations can provide real value in terms of new drugs and new markets. Since the pharmaceutical market is global and companies operate in different areas, getting insight from colleagues located in different regions can be very helpful. A number of companies have set up exchanges so that employees can work in different offices or departments for a period of time. People become better at communicating with each other and learn new skills, and they begin to look at the bigger picture for the company. When these people return to their home region or department they become vital links for collaborative efforts within the company. Communication is all-important in collaborations. If people are to get past the silo mentality in big organizations and truly exchange ideas then they need to understand the benefits of dealing with their colleagues.

HAMELIN. Based on prior experience working with several of the top 10 pharmaceutical companies in the industry, the best practice that I have seen is truly integrating the best commercial and marketing people with research at a very early stage in the development process. This integration should happen as early as Phase I to allow the design of the entire life cycle of a product across clinical and regulatory development all the way to the market. Unfortunately, often companies select junior commercial people to work with R&D groups and that typically results in failure. Not that these people aren't talented, but the more experienced and best marketing people will help craft the best product for a successful commercial launch. Companies with best practices have commercial and marketing people working with R&D at Phase I. Many companies do not start involving their best marketing talent until Phase III, which is a bit late in the process.

ERICKSON. If big companies want employees to change their behavior and collaborate more openly, they need to address organization,

What's Your Opinion?

2005 — A LOOK AHEAD

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A changing reimbursement landscape

In the upcoming year, the repercussions of the Medicare Modernization Act of 2003 (MMA) will impact the pharmaceutical industry on multiple fronts. Changes in reimbursement for physician-administered medications (Medicare Part B) will likely impact physician prescribing patterns and site of case decisions. Seniors' responses to, and ongoing impressions of, the Medicare Prescription Drug Benefit (Medicare Part D) have implications for the industry's reputation and the extent to which prescription drugs remain a flashpoint for public opinion. Furthermore, the inclusion of health savings accounts as part of the MMA is likely to fuel ongoing innovations in benefit design for the employer-sponsored insurance market. Without a doubt, the pharmaceutical industry will be facing a changing reimbursement landscape on all fronts.

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compensation, and control systems simultaneously. A basic rule is: "if you want someone to do something, pay 'em." If companies want intracompany/divisional cooperation, reward and evaluation systems must encourage such behavior explicitly. Additionally, team leaders must be empowered to direct individuals from different departments and have input into evaluation and compensation of these individuals. Corporate finance, legal, and other staff functions must be made more accountable to business units and collaborative teams.

CAUWENBERGH. Companies need to bring the product champion from marketing into the later stages of the development and regulatory process of a product and have this champion actively participate in planning and execution of these stages. They need to coordinate the data flow that goes to the public (conferences, and so on) with the regulatory strategy. Companies need to have realistic pricing discussions early on, before creating precedents in one country or another. And, they need to strive for one global core product message to avoid misuse of a drug in one region that could backfire on the global potential of the product.

FREIMAN. Cross-functional teams with some degree of power to drive products forward are absolutely essential. Team leaders must represent the best human capital that a company can provide, regardless of that person's functional area of responsibility.

BOILY. The implementation of global product-development teams that can bring a multidisciplinary approach to the table provides direction to ensure focused investment. The formalized communication process is now occurring at a far earlier stage in the development of a product than ever before. Equally, service providers must be able to provide global insight and services to meet those needs. Balancing U.S. market requirements with those of other parts of the world remains a key objective.

▶ PATIENT SAFETY

BARRETT. Patient safety is a cornerstone of clinical trials. But with the increasing pace of trials, it's no longer efficient to be reactive; proactive, real-time monitoring can increase the safety of those participating in trials, spotting potential interactions, and flagging common side effects. One of the ways to accomplish these goals is a Web-based solution with proactive notifications. The technology is available to manage this at a global level, so I think we'll continue to see a better level of patient safety.

BUA. Patient safety in clinical trials is fairly well-moderated and reasonably strong, given local IRB approval processes and patient-informed consent, so only marginal improvements can be made with respect to patient safety in clinical trials. The real focus should be on monitoring patient safety after NDA approval, during Phase IV studies, and prescribing uptakes, especially with respect to off-label use.

HADDOX. Prescription drug abuse is an emerging public-health problem that our industry should be addressing in collaboration with multiple private and public partners. For the first time, this year the President included prescription drug abuse as a key component of the Office of National Drug Control Policy. The abuse of medications, however, goes beyond prescription drugs, as a number of OTC products also are being abused. It is estimated that about one-third of all substance abuse today involves legal pharmaceutical products, often in combination with other licit or illicit substances. One especially vulnerable portion of the population affected by this pervasive, often regionalized problem is young people. Prescription drug abuse can only be solved by a collaborative effort involving law enforcement, schools, parents, community-based organizations, healthcare professionals, social-service agencies, regulatory bodies, and the pharmaceutical industry. Purdue has been working to combat the abuse and diversion of our major opioid analgesic, OxyContin Tablets, since 2000. We elected to get involved and become part of the solution, because we know it's a complex issue that law enforcement alone cannot be expected to handle. There's a lot that the pharmaceutical industry can, and should, do to help fight prescription drug abuse.

FREIMAN. Clearly since Vioxx, the so-called guardians of safety will have their hatchets out and sharpened. I personally don't think much is missing with regard to patient safety, as both the clinicians of industry and reviewing offices of the FDA have high-ethical standards. Perhaps an annual face-to-face follow up meeting on newly approved drugs would be in order to review any safety concerns or just to update both sides.

CAUWENBERGH. When studies are properly conducted, patient safety under today's standards is probably better protected in a study setting than in day-to-day life. I don't see a need for major changes in this aspect in the