



## **2009 Pharmaceutical Industry Perspective**

At the beginning of 2009, the global economic environment is still in a major state of flux. Parts of the world are already in recession, with others at risk – and there is legitimate concern about how deep and long the downturn will be. It is not yet clear what impact that environment will have on healthcare in general and pharmaceuticals in particular. In the United States, the actions of the Obama administration and Congress suggest they are committed to addressing healthcare issues as part of economic reform. The global economic slowdown will likely accelerate reform in other countries as well, whether in the form of increasing government demands for price cuts, as in Germany and the U.K., or encouraged use of generics, as in Japan.

In today's market, there are opportunities for pharmaceutical companies to take more dramatic action than they have to date. Developing new business models will allow companies to redefine the value of their own products. Exploring new partnerships with payors, regulators, pharmacists, and patients will generate added value for all pharmaceutical players.

The following pages lay out our perspective on the implications of developments in healthcare on the pharmaceutical sector and the trends we see for the coming year and beyond.

## **2008: Incremental Changes and Positioning for the Future**

Fundamentally, 2008 was a year for addressing structural and operational issues, determining where future growth will be found, and positioning the industry for reform and other changes.

The healthcare industry as a whole continued to grow in 2008, though stock market developments across all industries at the end of 2008 and beginning of 2009 have pushed down market caps. Pharmaceutical usage continued to expand, albeit more slowly than in previous years. At the same time, generics continued to pick up market share globally, regulatory environments around the world remained challenging, and health technology assessments in the U.K. and other markets constrained access to medicines. Finally, in the U.S., the recent economic downturn led to some contraction of pharmaceutical sales for the first time in years.

Healthcare stakeholders in the U.S. began to position themselves for the post-election healthcare reform debates, sending up trial balloons and taking preemptive actions to blunt criticism. Examples include the America's Health Insurance Plans' (AHIP) Guarantee Access Plan, in which the government covers the most costly cases, and the Pharmaceutical Research and Manufacturers of America's (PhRMA) revision of its marketing code to ban certain traditional sales practices (e.g., noneducational gifts, restaurant meals for healthcare professionals). As in the U.S., in Europe the pharma industry is seeing a shift away from the model in which the physician is the major stakeholder. Payor organizations are taking

---

on a more significant role, the distribution landscape is changing, and patients/consumers are taking on a larger role in healthcare decision making.

The industry continued to experiment on the supply side of the market. Retail clinics expanded and insurers became increasingly bold in exploring coverage for medical tourism for non-acute procedures. New intermediaries entered the healthcare information fray in earnest with the late 2007 launch of Microsoft Vault and early 2008 launch of Google Health, offering patient-focused health records and collaborations with other healthcare stakeholders to support adoption. Medical Home and payment pilots such as Prometheus continued to test potential new models of engagement and healthcare management.

Pharma companies reacted to narrow pipelines and constraints on existing products with significant operational restructuring. They announced more than 20,000 planned layoffs in 2008 to align cost structures to expected future needs, with sales forces taking a heavy hit. Simultaneously, pharma snapped up a number of biotech companies with interesting products and technologies to supplement pipelines. Roche's offer for Genentech and Lilly's acquisition of ImClone were among the largest. Some companies are also rethinking their overall business portfolios. For example, Novartis is placing a growing emphasis on consumers and product categories with potential for growth in emerging markets with the acquisition of a significant stake in Alcon, and Procter & Gamble is de-emphasizing its prescription pharmaceutical business.

Employers in the U.S. quietly pushed for reform but largely refrained from dramatic actions, with the exception of GM's announcement that it would be terminating lifetime healthcare coverage for salaried retirees beginning in 2009. We expect employers – who were clearly under pressure even before the economic downturn – to play an important role in shaping the actions of health plans and the government during healthcare reform discussions to come. At a minimum, we anticipate a continued rapid increase in benefit constraints. Benefit plans that shift cost to consumers, such as high-deductible health plans, are also likely to achieve further penetration.

On the brighter side, healthcare spending continued to expand in emerging markets such as China, India, and Brazil. A growing middle class, increasing government spending on healthcare, and greater industry focus on these expanding markets promise meaningful future growth opportunities.

### **Looking Forward: Taking Back the Helm**

Market and competitive pressures on the pharmaceutical industry, and the healthcare sector more broadly, create the challenge and opportunity for pharma to take back the helm with proactive approaches and business models that simultaneously address the following issues of healthcare access, affordability, and quality:

- Healthcare costs in the U.S. have continued a decades-long trend of exceeding the consumer price index substantially; an aging population and increases in obesity (and accompanying chronic conditions) augur continued strains on the system in developed countries. Payors continue to focus on options for managing price and utilization.
  - Access to care remains an issue, as evidenced by the wait times to see physicians in many countries and the 47 million Americans who are uninsured, with even more underinsured.
-

- The public more often views the pharmaceutical industry as part of the problem than as part of the solution. Pharmaceutical companies have spent billions of dollars looking for new treatments and supporting access to drugs for those who cannot afford them, but stories about me-too drugs, patent disputes, conflicting scientific studies, safety risks, and specialty treatments that cost tens of thousands of dollars per patient are more likely to make the news.
- Potentially transformational changes such as more broad and systematic use of evidence-based medicine (EBM) and electronic health records hold promise and risks. However, fundamental changes to financing and delivery models are necessary to make that potential a reality. The extent to which EBM and electronic health records will be blunt instruments or nuanced tools to shape behavior is unclear.
- In developing economies, healthcare affordability remains a challenge. The recession is slowing growth even in emerging economies, although opportunities remain.

Sources of profitability are also shifting. Large and global generics companies are maintaining pressure on the branded pharmaceutical industry and are well-positioned politically as “white knights.” Patterns of growth are changing worldwide, with the slowest growth expected in the U.S. and large European markets. Emerging markets are growing more rapidly, although the vast majority of sales and profits continue to be made in developed markets. Higher margins are migrating to specialty and biotech drugs as primary care and small molecule products continue to come under extreme competitive pressure. Historically, specialty and biotech drugs offered some respite from the highly managed and competitive world of primary care, but payors are increasingly scrutinizing these categories as well, and consumers are bearing more of the burden for high-cost treatments.

The pharmaceutical industry is undeniably under intense pressure, and the situation is likely to get worse before it gets better. Unrelenting pressure on prices and utilization, coupled with a weak flow of new products, creates an environment that most pharmaceutical company executives have not experienced in the course of their careers. As a result, many pharmaceutical companies have made significant pronouncements about operating differently. As we look forward, however, we believe that unless pharmaceutical companies regain control with respect to defining product benefits and risks and back up their intent with real innovative change in business models, their position will continue to deteriorate.

### **Regaining Control and Sparking Innovation**

Although the industry has understandably focused on sales and marketing models, pricing, reimbursement, and research and development (R&D) productivity, we believe it must address a fundamental underlying issue. Over the last several years, pharmaceutical companies have lost control of how the value of their own products is defined. Traditionally the industry presented the clinical benefits and safety risks of its products, with oversight from regulators. The industry was the primary communicator to physicians, patients, payors, and other decision makers.

More recently, many other parties have been stepping in to have their say about the benefits and risks of pharmaceuticals. Entities such as the National Institute of Clinical

---

Excellence (NICE) in the U.K., health plans in the U.S., and individual academics and clinicians are all weighing in on pharmaceutical products.

Pharmaceutical executives have taken some action—for example, increasing integration of the commercial and development sides of the business to ensure the commercial relevance of scientific and clinical innovation. The commercial side recognizes the declining value of the heavy “push model” of physician sales and is trying to redefine frontline marketing. Operationally, companies are streamlining, but are also taking a leadership role in adding safety and transparency in the supply chain. These initial moves make sense and are starting to take hold, but we believe that most of the industry must do much more to back up intentions with successful actions.

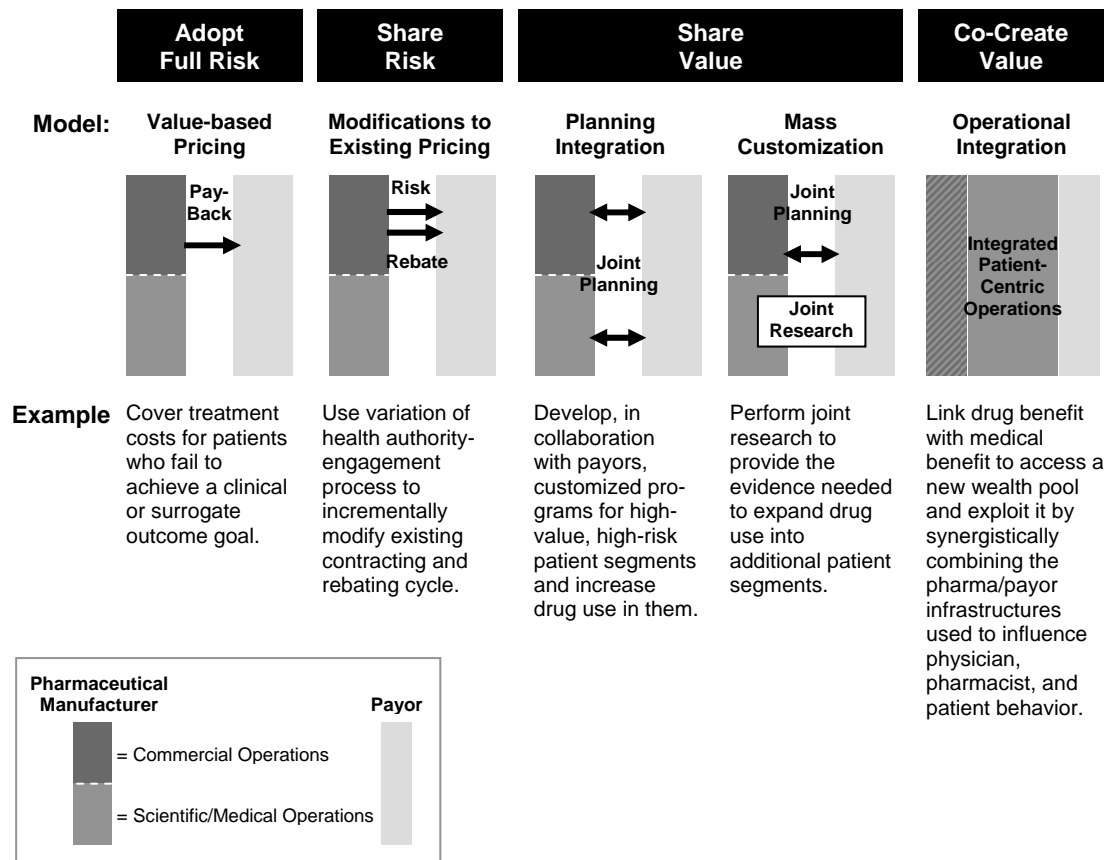
To regain control over their business and to take actions that truly innovate, pharmaceutical companies must initiate fundamental change. We see four ways in which pharmaceutical companies can go much further than they have to date.

- 1.) *Moving beyond concept to reality in building true collaborations with other healthcare stakeholders that are focused on improving overall patient costs and outcomes.* An important strategy is to engage with payors to do joint pharmaco-economic studies they both endorse, and to go beyond this measure to develop joint programs and capabilities that deliver product benefits and manage risks by changing physician and patient behavior.
- 2.) *Taking back control of the safety debate with information and supply chain innovation.* The industry will establish public-private initiatives with regulators to jointly gather, analyze, and report safety data—and ultimately efficacy findings—to address the negative consequences of the current debate over product safety. Companies will also strengthen the safety of the global pharmaceutical supply chain to minimize incidents related to counterfeit drugs.
- 3.) *Driving commercial value with new approaches to primary customers that go beyond shifting the mix and level of resources.* Companies need to adopt flexible models for marketing to physicians, integrating multiple channels of communication and interaction for priority practices. This lowers the cost of maintaining share, which means companies can direct their spending for upside opportunities. Companies will also continue to better understand and forge closer relationships with patients and consumers, consistent with the rising importance of consumer out-of-pocket expenses and the greater level of interest in personal care and individual health.
- 4.) *Assessing the pipeline portfolio and migrating it more aggressively to focus on novel specialty products with significant patient and payor benefit.* Clinical and commercial relevance should go into selection and validation of novel targets along with building biology capabilities.

### **Collaborating Around Patient Cost and Outcomes**

True innovation requires partnering with other stakeholders to drive value. Today most of the industry operates in zero-sum competition between the pharmaceutical manufacturer and the payor or the agent of the payor (i.e., the health plan, in the U.S.). We are beginning to see an emerging model focused on co-creation of value by making the entire pie larger for manufacturers, payors, plans, and complementary third parties as they share data and jointly move to improve patient-centric care outcomes, both clinical and economic. A variety of individual partnership initiatives are being tested (see Exhibit 1).

Exhibit 1  
Alternative Pharma-Payor Partnerships



Although no one is yet engaged in truly co-creating value, we believe there is potential. Successful companies will work with payors in joint pharmaco-economic studies that will allow them to create value through joint programs and capabilities to deliver benefits and manage risk. We are currently working with innovative pharmaceutical companies and payors to develop such collaborative ventures that go beyond the traditional pay-for-services model, which has only marginal benefits. In our experience, creating joint pharmaceutical-payor value is challenging but definitely possible.

**Taking Control of the Safety Debate**

How often do we hear about a new study that contradicts previous findings on the safety or efficacy of a pharmaceutical product? Such studies can result in consumer and physician concern and dramatic swings in patient utilization, as well as lawsuits.

Pharma has the opportunity to reposition itself as a partner with regulators to assess and manage safety issues through public-private initiatives to *jointly* gather, analyze, and report safety – and ultimately efficacy – data for products.

The FDA's Sentinel initiative, launched in May 2005, sets out to provide access to existing electronic health information, including claims data, emerging electronic health records, and diagnostic databases. The FDA would use these databases to monitor the safety of drugs and devices, and the Sentinel database will likely support Phase IV post-marketing studies and surveillance. The hope is to identify safety issues early on but to also discount early safety signals that do not emerge with a broader population. The eHealth Initiative (eHI), a private-public partnership, is currently conducting case studies for the FDA to understand how access to electronic health information will allow tracking of adverse events and support post-marketing surveillance.

By participating in the evolution of these initiatives, pharma can both position itself as an open collaborator in addressing public health challenges, and help ensure that the data, analysis, and findings built on these databases are fair and sound, reducing noise in the market.

Pharma also has the opportunity to strengthen the safety of the global supply chain for products, ensuring that only legitimate suppliers have market access as well as increasing public confidence in product quality. Discussions of item-level serialization in the pharmaceutical industry have been going on for years, and some companies have started serializing some products, but industry-wide adoption has yet to occur in the United States. European serialization efforts are more advanced.

Based on Booz & Company's interviews with more than 90 participants in the healthcare supply chain and our analysis of the economic impact of item-level serialization, serialization appears beneficial to the industry in terms of both economics and patient safety. Among manufacturers, benefits are primarily realized through increased sales due to reductions in counterfeit and diverted products. There are also very important indirect benefits related to patient and consumer confidence in the industry. As expected, benefits and costs vary significantly based on where an organization sits in the value chain.

In the U.S., at least 28 states have enacted varying product pedigree requirements – which, unfortunately, introduces the risk of creating a patchwork of standards. The federal Buyer-Matheson legislation introduced in April 2008, with a proposed gradual implementation starting in September 2011, has the potential to preempt all state product legislation, easing the burden on the supply chain.

Before federal legislation is enacted, pharmaceutical companies have the opportunity to take a leadership position on the issue. First movers may be able to differentiate on superior product safety. They may also be able to shape implementation standards and negotiate a preferred position with other supply chain stakeholders in exchange for joint implementation of desired technology solutions.

### **Driving Commercial Value through New Approaches**

Most commercial innovation in the pharmaceutical industry has been fairly constrained. After an initial wave of small-scale pilots, resulting in mostly cost-focused head count adjustments and minor collaborations with new stakeholders, companies have moved to more proactive approaches. They are shifting away from physician-based models to focus more on accounts. Companies are also adjusting resources to be more flexible – for example, through regional tailoring and increased focus on non-physician customers such as payors, pharmacies, and patients. Although these efforts have elements of the right approach, they remain somewhat limited. Most of these changes to date have focused on

---

pulling reps, not breakthrough models that create value through customer interaction. Many efforts are launched without the required capabilities, resource allocation, governance, and technical infrastructure to ensure success.

Pharma recognizes that the specific value proposition and positioning for every product is different; however, most commercial operating models have had only minor differences in approaches and capabilities. We believe that successful future commercial models will be increasingly tailored to customer perception of product value. In the eyes of payors, providers, and patients, product value is not monolithic. Different product categories create value in diverse ways, including clinical outcomes, cost savings, safety, unique means of delivery, patient satisfaction, price, and, in some regions, access and affordability. A commercial model that recognizes these important distinctions and reflects them in the go-to-market approach and supporting capabilities will be required in the future.

Commercial models can be tailored to deliver a clear and consistent message more efficiently by aligning drugs with a specific category of value, then building and aligning tailored capabilities to support the different value-based models. We believe customers see three fundamental sources of pharmaceutical value:

- *Medical management* products exhibit clinical differentiation with desirable cost-benefit outcomes. The payor is a key potential customer and partner in reaching physicians and patients. Payors, in working collaboratively with pharma companies, benefit from enhanced influence on physicians and patients to deliver improved patient outcomes at lower costs.
- *Premium brands* exhibit some clinical differentiation, but the differentiation may be one of a number of characteristics on which the product competes. For these products, which offer high revenue potential, payors will be less inclined to drive access and reimbursement. Pharmaceutical companies need to build patient preference directly with an economical model for selling to physicians. This would involve lower-cost channels to reach physicians and consumers, with involvement from specialty pharmacy and pharmacists.
- *Mature products* lack recognized advantages (in terms of either clinical superiority or patient preference) compared to generic products that could potentially substitute for them. The pharmacist and other channels are important gatekeepers or promoters for these products. Carefully considered pricing and efficient marketing become keys to profit.

By tailoring commercial models and building capabilities to explicitly address each of these sources of value, companies can significantly improve commercial effectiveness and efficiency. The required changes in operating models, which create capabilities to provide a broader set of stakeholders with tailored services and interactions appropriate to each category, can drive better alignment with customers in a more efficient manner.

Looking beyond mature markets in Europe and the United States, it will be critical to capture a share of growth in emerging markets, such as China, India, Brazil, Russia, and other fast-growing economies, as the middle class develops and governments increase coverage. Securing that growth will require new operating models to address the barriers to appropriate drug utilization: awareness, accessibility, affordability, and compliance. To get a toehold in emerging markets, companies will need to better understand the needs of

---

new consumers and manage the flow of information, as well as drug, financing, and patient support processes, in new and more effective ways.

Operating models will include innovative options for ensuring patient access to treatment. In India, for example, over-the-counter (OTC) manufacturers are trying to expand access in rural markets by launching a pilot with the postal service to sell OTC medications alongside stamps and envelopes in three regions. New models will also include novel approaches to addressing affordability constraints. Our research has identified multiple options for tackling these economic issues, but also suggests that all options are not created equal. Meeting customer needs and growing a presence in emerging markets will require new levels of creativity as well as dedicated talent and resources.

### **Migrating and Strengthening Pipeline Portfolios**

The pharmaceutical industry continues to struggle with product innovation, productivity, and output in the R&D process. Based on our proprietary analysis of phase II and III R&D pipelines over the last 10 years, we believe the industry can enhance innovation if it backs up intentions with action. For example:

- Despite stated intentions, pharma has failed to redirect pipelines to novel breakthroughs. As a whole, the industry reduced later-stage pipeline products against novel targets from 40 percent in 2000 to 36 percent in 2004. In 2008 the figure was down to 29 percent. Only four major companies increased their emphasis on novel targets between 2000 and 2008. Although there is no right or wrong mix of novel and known targets, the industry clearly has been slow to move away from historical approaches to discovery.
  - A number of pharmaceutical companies launched initiatives to improve discipline and commercial input into the development decision-making process over the last five to seven years, with little to show for it. The success rate of phase III compounds dropped from 45 percent in the late 1990s to 32 percent recently. The organizational change implemented by several large pharmaceutical companies to strengthen commercial input into phase III decision making and prioritization has had some beneficial effects. In our view, however, this type of change does not sufficiently address all the capabilities needed to improve phase III results. For example, improved safety analysis and assessment capabilities are a key requirement. In our experience, disciplined and dispassionate senior management involvement in portfolio prioritization, based on objective, high-quality evaluations, is key to bringing new products to market successfully.
  - Looking earlier in the development process, phase II success rates have also declined, falling from 15 percent in the late 1990s to less than 10 percent. This drop occurred despite the shift away from novel targets, which tend to drag down success rates. We believe the industry can do a much better job of validating novel targets, especially with enhanced biology capabilities. It is interesting to note that the industry has been moving away from dedicating resources to biology. For example, the proportion of biologics in the phase II and III pipeline has declined over the last eight years, from 22 percent to 20 percent. More importantly, spending on biology as a percentage of total discovery is down.
-

---

## Leveraging Market Uncertainty to Drive Structural Change

Slowdowns or periods of uncertainty can yield unique strategic opportunities. In a boom, it is difficult to gain relative position. Ironically, in a recession it can be easier to take stock and reconfigure for enhanced agility and profitability. Constraints on growth and profitability can create a burning platform for change and support strategic, structural changes in the operating model rather than hasty, across-the-board cuts at the margin.

For companies with solid balance sheets, uncertainty creates the opportunity to make strategic acquisitions and even redefine the business. The greatest benefit of hard times is the chance to ask basic questions about strategy and to act on the answers: What will be the source of our profits in the future? What businesses should we get out of? Are our organizational processes undercutting the value of our strategy? Do we really need to manufacture our own products? How can we align our R&D, marketing, and operations to drive faster growth?

Companies need a sharp focus on operational fitness, clarity on what is central and what is superfluous in the portfolio, and a strong sense of which capabilities need to be enhanced or built for future market success. We have seen a transition to this new reality come at astonishing speed in the financial sector. The pharmaceutical industry has the opportunity to move at a more deliberate yet urgent pace – but needs to act now.

2009 will be a challenging year. In addition to working to shape the external environment, the pharmaceutical industry also needs to be systematically reposition itself internally for long-term growth.

Charles G. Beever  
Partner  
charley.beever@booz.com

Richard C. Edmunds  
Partner  
rick.edmunds@booz.com

Rolf Fricker  
Partner  
rolf.fricker@booz.com

Anurag D. Gupta  
Partner  
anu.gupta@booz.com

Robert Hutchens  
Partner  
robert.hutchens@booz.com

Danielle Rollmann  
Partner  
danielle.rollmann@booz.com