

# Global Research Report Vision & Reality, 7<sup>th</sup> Edition

**Customer Value Integration –  
How to Re-Tune Pharma’s Commercial Model  
in Light of Changing Stakeholder Influence**





# Executive Summary

The pharmaceutical industry is undergoing a significant transformation - an observation which is almost commonplace given the numerous changes and complex adjustments big pharma players are currently implementing, and have been implementing in recent years.

At Capgemini's Global Life Sciences practice, we are both participants and observers of this transformation.

- We are in the middle of it, assisting executives throughout the industry and across global markets to evaluate alternative business models, pursue new customer segments, make operations more sophisticated, and realize the value of new systems.
- In addition, our clients present us with challenges to produce original thought leadership, provocative hypotheses, and innovative approaches for corporate initiatives.
- Most importantly, we have the intellectual curiosity and the professional commitment to make as much of a difference as an outside advisor, coach, and partner can possibly make during this spectacular transformation period in our industry.

With all these changes taking place – from detailing to promotions, from reimbursement to treatment guidelines – we sought input from executives in leading pharmaceutical companies on both sides of the Atlantic. These included distinguished physicians / thought leaders in New York, and selected executives in Europe and the U.S. We engaged analysts at Capgemini's Strategic Research Group, one of our Centers of Excellence. We also frequently gathered together our most senior team members over a period of more than six months. The objective was to distill the shifts that are most impacting the market, to identify the underlying drivers, to scan and evaluate company initiatives, and ultimately to identify the factors that make up the new commercial model in big pharma.

What we found is a type of Forward Integration that appears to build on a trend we discovered a few years ago: the evolving role and increasing importance of commercial business functions with regards to value creation.

In 2006, we discussed “Early Commercialization” for our Vision & Reality study, arguing that commercial input is needed much earlier in the value chain than traditionally occurs.

Today, we are arguing that “Customer Value Integration” is a form of Forward Integration, specific to the pharmaceutical industry, which complements the traditional value creation delivered by R&D. Customer Value Integration provides the opportunity to branch out to various stakeholder and customer markets in the pursuit of additional and more-than-incremental value.

Clearly, all major pharmaceutical companies are refining their business models; making strategic acquisitions, shedding non-core assets, etc. – some with significant success, others without apparent reward. A form of Customer Value Creation is inherent in many of these initiatives, as we discuss in this document:

- A leading global biopharma player develops a dedicated reimbursement support and disease management function to facilitate patient access to sophisticated products.
- A leading global pharmaceutical company contracts with a large U.S. state to provide prescription drugs to the elderly in exchange for offering exclusive disease management services to certain patient populations on chronic medications. This offer gives the manufacturer access to valuable prescription information and provides opportunities for prescription reminder calls to patients to raise compliance.
- A leading pharmaceutical company seeks to better understand public health entities in the U.S. – interested in serving them more effectively, through an improved segmentation-based approach.

However, responses from study participants suggest that there is a perception gap in many corners of this industry: between how executives view the market (and respond to it), and how the market evolves (and with what speed). Relationships with payers appear fairly strained, while physicians are looking to pharma for help.

Beyond case studies, we offer examples for Customer Value Integration in various customer segments, following the established “P-P-P” (physicians, payers, patients) model of commercial pharma. We detail lessons from Forward Integration in other industries and we propose the set of new competencies pharma has to develop and refine in order to meet today’s challenges.

Ultimately, Customer Value Integration will take different shapes and forms, depending on an individual company’s therapeutic area focus, product lifecycle stages and, of course, the nature of the product.

We hope that this document offers inspiring and thought-provoking insights.

April 8th, 2008  
New York, NY

#### Study Directors

  
Dr. Peter Barschdorff

  
Thomas Forissier



# I. Study Overview and Design

Sales and marketing teams at pharmaceutical companies have a tendency to think of physicians before all other stakeholders. Despite increasingly intensive and expensive efforts to woo these physicians, sales have increased only marginally. This is the result of a shift in influence where physicians are slowly, yet surely, sharing or passing on control to other stakeholders that influence, or even dictate, prescribing behavior.

Nonetheless, most pharmaceutical companies are not adjusting their strategies fast enough to reflect rapidly changing market realities. Instead, the majority of companies continue to focus on those who write prescriptions, while overlooking the growing influence that patients, payers, regulators, and pharmacists have over which prescriptions are written and which drugs are actually dispensed. To remain profitable, pharmaceutical companies must change the focus of their efforts.

► **To succeed, pharmaceutical executives must understand and adapt the commercial model to the changing landscape**

Each year since 2001, Capgemini's Life Sciences practice has examined a specific topic that is both timely and urgent for the life sciences industry. We conduct a global study on this topic and publish the resulting thought leadership as part of our annual Vision & Reality series.

For this current issue, we assessed how pharmaceutical companies are responding to shifting stakeholder influence: the declining influence of physicians and the increasing influence of private payers, governments, and regulators.

Within the pharmaceutical industry, sales and marketing efforts have traditionally focused on physicians. The reasoning was that physicians write prescriptions, so efforts to convince them of the utility of a treatment should boost sales. Significant sums of money continue to be spent on sales representatives who target physicians, physician-targeted advertisements, and medical education events. These investments are no longer generating the expected returns. Indeed, pharmaceutical companies have announced massive layoffs among sales representatives, realizing that expanded sales forces do not result in expanded sales.

Though physicians still write prescriptions, the stakeholder landscape is now much more complex, and prescribing behavior is increasingly influenced by indirect forces. Regulators (such as the FDA and the EMEA), and the media highlight safety profiles. Patients demand high standards and access while payers want access and affordable prices. For any one disease, there are many treatments, each with its individual effectiveness, safety profile, side effects, and cost to consider. In addition, several stakeholders are now demanding extra services, such as reimbursement support, disease management, health screening, or diagnostic support. Depending on the stakeholder, some of these services are more important than others. Physicians, caught in the middle, are feeling the strain.

Pharmaceutical companies are in the middle of a significant transformation. From their viewpoint, it is a challenge to create high-value products, not just because of the increasing burden of proof of drug utility and expensive R&D costs, but also due to the difficulty in predicting the extent to which a product will be valued and adopted. To assess the value to stakeholders, pharmaceutical companies must weigh the relative importance of these stakeholders and consider their individual needs. Similarly, they need to find smarter ways to segment their respective markets and fine-tune their approaches to different market segments. Without such consideration, pumping more money into physician-directed promotions will continue to provide less incremental value.

**► This report builds on expertise from multiple stakeholders in multiple countries**

To understand the existing state of affairs, we solicited expert input by reaching out to over 100 pharmaceutical executives worldwide, predominantly representing “big pharma.” Responses came from the U.S. (approximately two-thirds), Europe (approximately one-third), and from a small number of executives representing the growing markets of Asia and South America. Executives covered a range of functions including pricing, marketing, medical affairs, managed

care, science, procurement, sales, and commercial operations.

With input from these executives, we concluded that the biggest shift in stakeholder influence is from physicians to payers. We drilled down into these two groups through payer interviews (a half-dozen payer executives, from both Europe and the U.S.). We also engaged an independent physician panel of nine renowned medical thought leaders from the New York metropolitan area, representing select therapeutic areas, prestigious medical centers, and the admissions office of one of the leading American medical schools.

Finally, we supplemented our findings with secondary research conducted by Capgemini’s Strategic Research Group. The purpose of this research was to substantiate our insights which suggest that the new commercial model in the pharmaceutical industry is, in effect, the result of a horizontal shift in value creation: complementing risky and extensive R&D towards the innovative and entrepreneurial meeting of specialized customer needs – a model we have labeled Customer Value Integration.

Output from our original primary research is integral to this report and several key charts are presented here. On an individual basis, we are also making more comprehensive, in-depth briefing books available to clients and study participants.

## II. An Outdated Commercial Model: Poor Results and Market Shifts

The pharmaceutical industry once described itself as a safe investment, but recent trends no longer support this claim. In the past ten years, the Amex pharmaceutical index has underperformed the S&P 500. Morgan Stanley indices show that health-care payers have been a much better investment over the last decade, with an annual growth rate of 20.7%.

Other industries achieve much higher returns. Even the beleaguered automakers have lower ratios of sales expenses to sales than pharmaceutical manufacturers. For every dollar that automakers spend on sales expenses, they earn back \$7.57 in sales; for pharmaceutical manufacturers, the return is a meager \$2.15. This figure is almost exactly the same across multiple pharmaceutical companies, suggesting that different companies are largely using the same commercial model.

Since Prozac's fall in 2001, pharmaceutical companies have entered an unparalleled era of patent expiration. At this point it is virtually common knowledge that this phase is expected to last until 2011 and will cause (or cost) the pharmaceutical industry to shrink by 15% of 2007 revenues. Fewer blockbuster drugs are in the pipeline to fill the gaps left by giants such as Pfizer's Lipitor. Indeed, there is no second Lipitor in sight. A generic entrant not only annihilates the sales of the copied, branded product, but it also severely affects prices and sales of all other products in the class.

**Chart 1** Pharmaceutical Stock Performance, Compared to Select Other Indices

Industry Group Stock Indices Re-based – CAGRs 1997 bis 2007

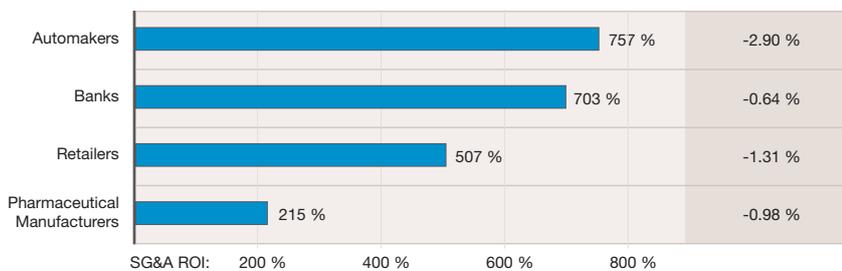


(31. Sept. 1997 = 100 %), Sept. 1997 - Sept. 2007

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**Chart 2 Comparative Industry SG&A ROIs**

Rate of Return on Commercial Investment (using SG&A as proxy), U.S., select industries (2006)  
CAGR 1997-2006



\* Industry sectors measured as aggregation of 12 or more of largest companies in sector

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These examples are not exceptions, but provide evidence of more challenging business conditions. A shortage of new products coupled with a shorter exclusivity period for the products that succeed has already challenged the marketplace. To counteract the decline in R&D productivity, pharmaceutical companies have been anxiously trying to fill uncertain pipelines by purchasing smaller biotech firms and molecules in development, or by partnering with other companies to mitigate development cost risks. Companies are pursuing mergers and acquisitions, diversifying into generics, or expanding their franchises beyond pharmaceuticals. Surprisingly few have focused successfully on improving effectiveness in areas that could truly improve returns all the way from R&D to manufacturing, supply and distribution, and commercial operations. There is a lot of trial and error for the companies to deal with increased improvements – but very little success in generating new long-term value.

## Market Shifts Abound

### Detailing

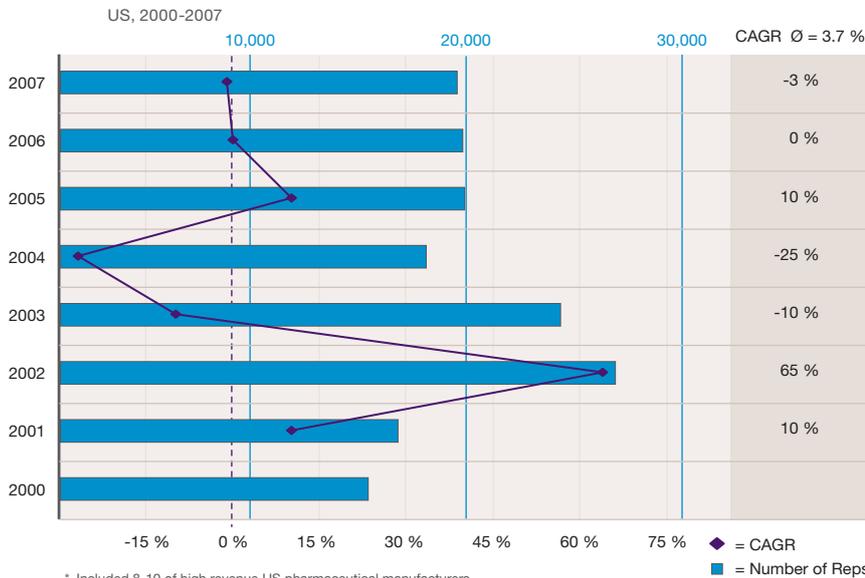
**Old Model:** Sales representatives are the best way to reach physicians

**Shift:** Sales representatives, the traditional means of reaching physicians, are becoming less effective

Today, many sales representatives find themselves visiting receptionists rather than physicians. In many cases sales representatives' direct contact with physicians is tightly controlled or even prohibited. If a sales representative is able to see a physician, the average visit in the U.S. lasts 60 to 90 seconds. And still physicians complain. Although European visits are longer, the trend of limiting physician access remains. For physicians, it seems that the ideal sales representative is someone who silently drops off samples (and the occasional free lunch). Without the expectation of receiving samples, nearly two-thirds of physicians would likely forbid sales representative visits.

In the U.S., legislation limits sales representatives' discussions with physicians (the 1996 Health Insurance Portability and Accountability Act; the 2003 Privacy Rule and Security Rule). They cannot ask doctors about specific patients, but must instead use hypothetical scenarios to explain how a drug could be used. While the original legislation has been in place for over a decade, much confusion still exists over what is allowed and what is not. Sales representatives are rarely permitted to enter examination rooms and must be monitored throughout their visits. In fact, some physicians believe that sales representatives should not even visit the office if patients are present, since this could allow outsiders to deduce a patient's condition, particularly in specialists' offices. To avoid accusations of non-compliance, some offices deny sales representatives' visits altogether.

**Chart 3** Average Number of Sales Reps per Major Pharmaceutical Company\*



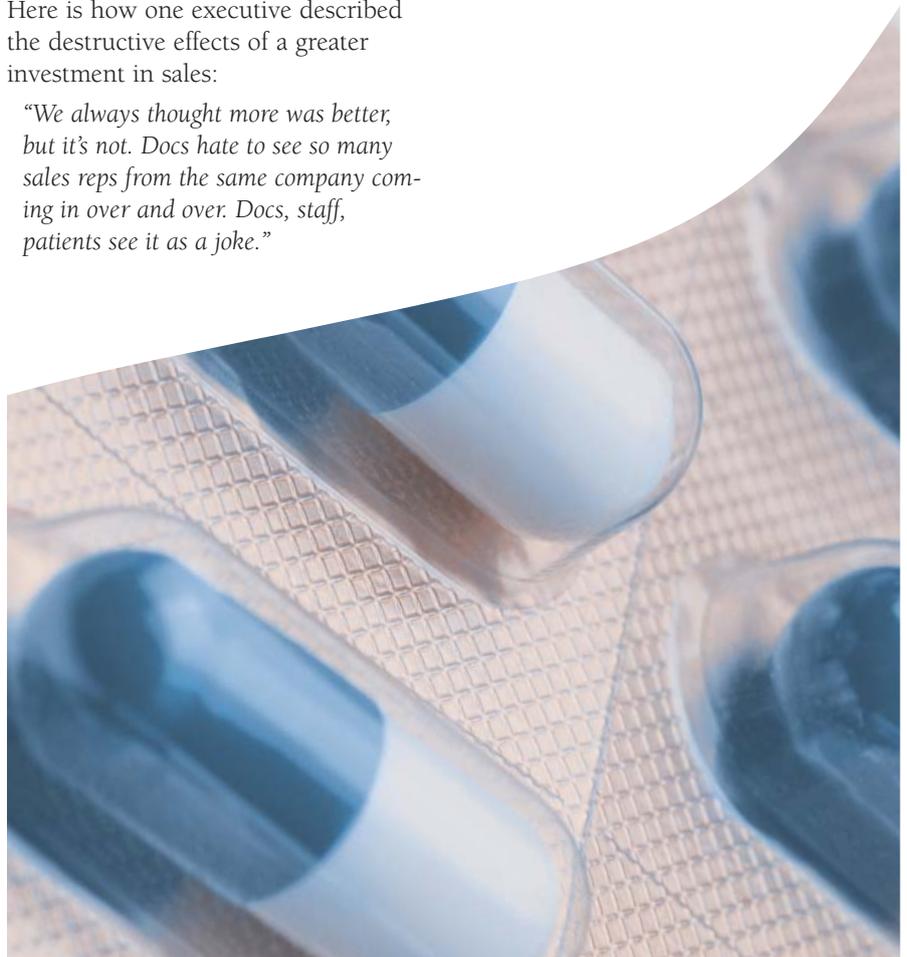
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With sales representatives becoming more limited in their ability to see physicians for an appropriate amount of time, the quality of the visit has diminished greatly. Physician recall of marketing messages declines as messages are flung at them in a sales representative's desperate attempt to leave an impression in a short time. There are virtually no opportunities to discuss new clinical findings. Even the welcomed function of delivering samples has become difficult in highly controlled or restricted settings. As the quality of the visit has decreased, so have returns.

In 2002, many companies boosted their sales force numbers to support increased product launches and acquisitions. Companies soon realized the diminishing returns in quality and duration of visits and in ROI. They cut back on the investments in the ensuing years. However, from 2000 to 2007, the number of sales representatives still increased at an overall compound annual growth rate of almost 4%.

Here is how one executive described the destructive effects of a greater investment in sales:

*"We always thought more was better, but it's not. Docs hate to see so many sales reps from the same company coming in over and over. Docs, staff, patients see it as a joke."*



### Healthcare Financing

**Old Model:** Healthcare costs used to be much lower – leaving room for healthy drug pricing

**Shift:** Healthcare reforms are resulting in pricing pressure, squeezing pharmaceutical profits

The costs of healthcare continue to grow at an unsustainable rate. As both governments and payers look for ways to reform healthcare, and thereby cut costs, prescription drugs are an obvious candidate.

drugs and as politicians seek to demonize the drug industry:

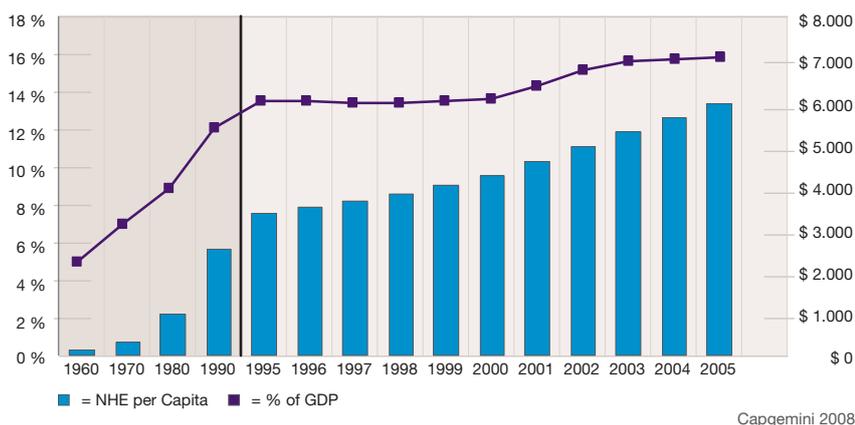
*“Almost every issue we have had as an industry you can trace to an almost ‘tobacco-like approach’ to public policy and advocacy. Right now Washington is vilifying us...this will carry over to the general population. This will also shift as people start paying for drugs on their own: as soon as people are in charge, they will be more sensitive to policy debates.”*

As polls have found, the public’s attitude toward pharmaceutical companies remains poor, despite a spike in advertising to mitigate negative images. The pharmaceutical industry is not viewed as trustworthy by patients, providers, and payers alike.

Almost all Western countries have begun enforcing price cuts or otherwise restricting reimbursement by limiting patients’ access to drugs. For example, the UK recently announced new pricing regulations. In Germany, the Institute for Quality and Efficiency in Healthcare has impeded reimbursement for innovative drugs like insulin analogues.

Despite its fragmentation and complexity, the U.S. has long provided a security blanket for pharmaceutical companies. Its 300 million potential consumers represent nearly half of the world market in sales. Pharmaceutical companies have generally been free to charge what they choose, but new policies are threatening this free-price refuge. In January 2007, the House of Representatives passed legislation allowing the Department of Health and Human Services to negotiate drug prices. The bill has been stalled since fall 2007, but its progress to date illustrates a profound shift in policy.

**Chart 4** U.S. National Healthcare Expenditures and Percentage of GDP



Historically, the pharmaceutical industry has justified prices by pointing to the need to fund costly and uncertain R&D projects, and to the fact that prescription drugs were a means of avoiding much higher cost for other treatments and / or hospitalization. But today, pharmaceutical companies have dwindling pipelines, a fact that makes it harder to defend drug prices with high R&D costs. In addition, the notion that drugs generate healthcare savings is increasingly coming under attack.

One interviewed pharmaceutical executive predicted that pricing pressure will continue to increase as individual patients bear more of the costs for

## Payers

**Old model:** Payers had limited power and reimbursed healthcare cost generously

**Shift:** Payers are exercising more influence and have tightened reimbursement

Payers are now focused on controlling costs by managing three challenges: specialty drugs, expanded coverage, and patient consumerism. Increasingly, payers hope to control costs of biologics. For example, Cerezyme (a drug used to treat Gaucher's disease which is caused by the lack of the enzyme glucocerebrosidase) costs around \$200,000 in the U.S. for a year's treatment. The traditional copayment scheme is generating serious friction. Patients are unaccustomed to paying thousands of dollars out-of-pocket for life-saving drugs, and several mainstream media accounts have chronicled the financial struggles of cancer patients. Thus, payers and regulators are looking for more sophisticated ways to intervene. These include shifting costs (or risk) to providers or making them more accountable in other ways. Additionally, high-cost patients are being shifted to comprehensive disease management programs. Such highly interactive programs increase payers' influence over patients. In addition, payers prefer tools that limit utilization of high-cost drugs, such as step therapy, as well as stiff requirements for pharmacoeconomic evidence to establish drug placement on formularies.

Private payers have been consolidating, thus increasing their leverage over pharmaceutical manufacturers. However, most pharmaceutical executives feel that, ultimately, government policy makers will have the greatest influence over the pharmaceutical market. Since these policy makers owe their positions to voters, payers also see patients as becoming more empowered than ever to direct prescription decisions. Thus, even as non-government payers' power over pharmaceutical manufacturers increases, private payers feel that their own power will soon erode.

Here is one U.S. payer's prediction:

*"In the coming years, reimbursement is likely to move towards a public payers system, and therefore, payers will be subject to more influence of a national reimbursement agency."*

Payers are eager to avoid patient outrage, and so prefer to enforce treatment guidelines drafted by trusted third parties. For example, U.S. insurance companies are concerned that lawsuits over care denial threaten their image and balance sheets. In the UK, citizens held protests over the inaccessibility of the high-cost cancer drug Herceptin, forcing NICE (National Institute for Clinical Excellence) to accelerate procedures that allowed distribution.



## Treatment Guidelines

**Old model:** Treatment guidelines are provided by the medical professional community

**Shift:** Treatment guidelines are effectively provided by centralized drug evaluators and payers, squeezing manufacturers

Across the world, stakeholders are tightening reimbursement, influencing both product utilization and price; payers are strengthening mechanisms to keep healthcare spending down.

These mechanisms are more forceful than ever, because payers and governments have recently taken a more centralized approach to drug evaluation, exerting more and more influence over prescription drug reimbursement. Importantly, payers and governments have begun issuing their own prescribing and treatment guidelines, which physicians have a strong incentive to adopt. These guidelines essentially set the options for patient treatments and prescribers' choices. Drugs not listed on these guidelines are severely affected.

Perhaps the best example of a centralized drug evaluation group is the UK's NICE. Created in 1999 to counteract a policy in which the availability of certain drugs depended on where patients lived, NICE dictates drug coverage through an analysis of cost-effectiveness. Drugs with high costs and uncertain effects come under particularly harsh scrutiny.

To gain optimal reimbursement for their products, pharmaceutical companies must maintain a careful balance between effectiveness and cost. The institute particularly values results from head-to-head studies:

expensive, lengthy trials that pharmaceutical companies have traditionally avoided. However, as many industry experts claim, without such data medications remain in limbo; neither accepted nor rejected. Formulary decisions can be deferred indefinitely. The burden of proof is on manufacturers.

Drugs without pharmacoeconomic data appear routinely delayed or denied reimbursement in the UK. Less than half of cancer medications are available to British patients within five years of launch. In August 2006, NICE recommended against reimbursing for Avastin and Erbitux even while acknowledging that the drugs worked. The ultimate rationale against reimbursement was not lack of efficacy but high cost. Germany's IQWiG (Institute for Quality and Efficiency in Healthcare) issued a negative opinion about Pfizer's Exubera. This step, together with slow market uptake in other markets, contributed to Pfizer discontinuing the marketing of the drug (and taking a \$2.8 billion write-off).

Critics of NICE and IQWiG maintain that centralized drug evaluation agencies waste resources by erecting yet another hurdle and delaying patient access to novel treatments. They believe that a more effective means of reducing cost is to focus on other areas, particularly decreasing the number and length of patient hospitalizations. Moreover, improved savings could be achieved if cost issues are addressed over the entire course of a disease or treatment, rather than considered in terms of the effects of individual drugs. And, agencies like IQWiG may well obscure the overall drug approval and reimbursement process by establishing procedures



and criteria of cost effectiveness evaluation that are not sufficiently transparent to industry decision-makers. (In Germany, criticisms of the methodology used by IQWiG have led to revisions of several of its various methods.)

In the U.S., centralized drug evaluation is in its infancy. The Agency for Healthcare Research and Quality (AHRQ) is influential among payers, but its influence on the pharmaceutical industry is less pronounced because its recommendations are not binding and they exclude cost as a basis for review. Additionally, the U.S. healthcare industry has no incentive to consider the long-term perspective of patient care because each payer in the U.S. managed care market usually covers working-age and younger patients for only a few years at a time. The demographics of patients are very different for those on Medicare, which would benefit from viewing patients with a long-term perspective. As the government realizes the benefits in cost savings in managing diseases over the long term, the U.S. model may shift to that of the EU, where reimbursement and pricing is highly centralized. Centralization of reimbursement and pricing decisions in the U.S. would be a major threat to the pharmaceutical industry.

However, payers are analyzing an ever increasing number of patients and their conditions. Special populations who were previously “off the radar” are now coming under scrutiny; improved data collection and data mining allow payers to analyze drug utilization and efficacy in small, high-cost populations, which can now be targeted for cost cutting. The benefits of medicines are greater in some populations than in others. In the short

term, payers will provide reimbursement for these drugs. But in the long term, as payers assess the results in patients, the burden is upon physicians to prove high efficacy and justify high costs. Patients without adequately beneficial results may have to pay back those reimbursed costs, presumably because payers come to believe that treatment efficacy is compromised due to patient non-compliance, e.g., irregular medicine taking, unhealthy lifestyle. Conditions for eligibility for treatment and “conditions lists” (detailing which patients are eligible to receive reimbursement, at which levels, on which conditions – age, lifestyle, etc.) have never been tighter.

Despite the number and variety of indications approved by government regulators for any particular drug, agencies and payers are narrowing the number of indications for which they will provide reimbursement. In the UK, NICE recently announced that it would limit access to four popular drugs used to treat symptoms of Alzheimer’s disease. The institute went so far as to ask doctors not to prescribe these drugs to newly diagnosed patients.

### Generics Switching

**Old model:** Transition between shift in prescriptions from branded to generic product took several months

**Shift:** Transition in market share to small-molecule generics has been accelerated by payers

Pressure from small-molecule generics is increasing. In 2006, nine of America’s top ten high-growth pharmaceutical manufacturing companies made generic drugs. Today, generics are making new inroads. Generics manufacturers have become more adept at challenging patents. Among

all stakeholders, only branded manufacturers seem dismayed at the rise of generics. Payers, governments, physicians, and patients (i.e., most other healthcare stakeholders) view generics favorably.

Payers in the U.S. and other key markets (including Australia, Canada, France, Germany, Sweden, and the UK) are promoting generic substitution as a cost-cutting mechanism. Payers push pharmacists to switch to generics, in part by allowing them to earn higher margins with generic drugs. In some cases the switch from a branded drug to its generic equivalent is automatic, unless physicians pro-actively prohibit substitution when they write a prescription. In the U.S. physicians must remember to prevent substitution by checking a box marked “daw” (dispense as written); otherwise both patients and pharmacies may be incentivized to receive generics.

### Drug Substitution

**Old model:** Drug substitution was not an acceptable practice

**Shift:** Drug substitution has increased considerably through payer influence

Payers and regulators influence drug use and price beyond the promotion of generics. Once considered unthinkable, substitution of drugs is now routine. Whereas payers once exerted their influence within a class of drugs, they are now pushing physicians for therapeutic substitution across classes. In the U.S., many payers place newer “me-too” treatments in less favorable tiers on formularies or keep them off formularies altogether.

For example, clinical evidence suggests that branded COX-2 inhibitors (such as Aleve) and generic NSAIDs (such as ibuprofen) provide similar levels of pain relief. However, older NSAIDs can be dangerous for patients at risk for certain gastrointestinal

events, such as bleeding and ulcers, so physicians have generally preferred COX-2 inhibitors. Now payers can conduct risk profiling to identify at-risk patients; non-risk patients are steered to cheaper NSAID therapies.

Within a class, pricing effects can be even more insidious. Payers compare prices and put pressure on manufacturers to reduce prices to match the cheapest similar alternative. This therapeutic reference pricing has become very common. Once one drug in a class goes off patent, the prices of the newer drugs in that class can plummet.

### Physician Prescribing Information

**Old model:** Access to physician prescribing information was virtually unlimited for sales managers and representatives

**Shift:** Access has been reduced as regulations increasingly prevent pharmaceutical manufacturers from identifying high- and low-prescribing doctors

Increasingly, drug sales teams are prohibited from receiving information about individual physicians. Physicians accuse sales representatives of using data about prescribing habits to pressure them into increasing prescriptions for particular products.



Such complaints also prompted the American Medical Association to create the Prescribing Data Restriction Program, which took effect in July 2006. Physicians can opt to prevent a range of data from being provided to sales representatives and managers. Sales representatives can see information such as quantiled prescribing volume for given therapeutic classes, but not individual brands or products.

Mounting complaints from physicians have led to pending legislation to restrict access to this information in several states, including Arizona, California, and New Hampshire. New Hampshire is particularly restrictive. In the summer of 2006, the state passed a law barring pharmacies and health insurers from selling physician-level data to the data aggregators (such as IMS and Verispan) that sell this data to pharmaceutical companies.

In the fall of 2007, IMS and Verispan pursued legal action against New Hampshire on the ground that its law violates free speech. The two companies are comparing themselves to newspapers, which also profit by reporting information. New Hampshire represents only 1% of total prescriptions. While the data providers prevailed, New Hampshire and other states continue to press their case. Pharmaceutical companies may have to fear much compromised prescribing information, a step that will make effective and targeted marketing approaches much more difficult to achieve.



# III. Stakeholder Perceptions: Challenges and Opportunities

It is intriguing to compare pharmaceutical executives' views of the commercial model with our perspective of the industry landscape – the outdated model, the shifts in stakeholder influence, the strong gain in payer influence, the emergence of new guidelines and practices, etc. With the benefit of insight into numerous company situations, and informed by secondary research, our assessment of the previous chapter suggests a much more severe shift than many executives appear to appreciate.

## A Perception Gap?

### The nature of the changes

Overall, a significant majority of the executives who provided input to this study found the market changes to be of a structural nature, i.e., responses to fundamental shifts in the market. While this view is most aligned with our point of view, it is only supported by about half of the universe of participating individuals.

The other half of respondents views the changes as incremental or temporary in nature.

When we asked respondents to elaborate on their “incremental” answers, we learned that many acknowledged structural changes in the market, but emphasized the incremental industry response to these changes. Industry responses may be incremental due to the regulatory restrictions imposed on the pharmaceutical industry, and the complex, large-scale, global model of the leading pharmas, requiring significant efforts to transform this model.

The “temporary” answer was harder to understand. It may reflect a small number of executives representing a particular view idiosyncratic to their respective business context.

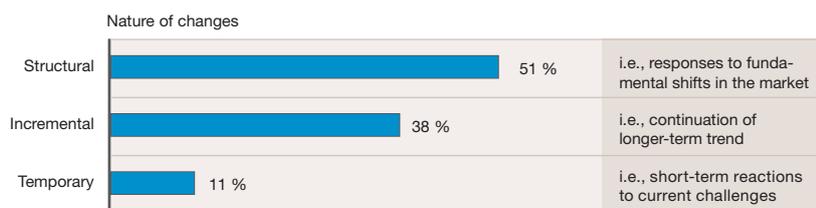
### Drivers of change

When asked about the factors underlying the changes, pricing, policy, and regulatory influence emerged as the top three drivers (chart 6).

Note that “payer / pricing pressure” was listed by almost eight in ten individuals, with “government influence” and “regulatory requirements” far below (slightly over and slightly under 50%, respectively).

**Chart 5** Pharmaceutical Executives' View of the Nature of Market Changes

In a nutshell, what is your view of the nature of the changes we've started to see in how pharmaceutical products are brought to market?



n = 95, % of Respondents

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Clearly, pharmaceutical companies have very little control over the top three stated factors, neither has the industry in general. In fact, the pharmaceutical industry is usually not invited to participate when pricing, policy, and regulatory decisions are made by government decision-makers. Yet, according to our findings, the business impact of these factors is considered significant – a fact that may explain the current unease in many pharma executive suites.

Interestingly, pharmaceutical responses were consistent across executives in the U.S. and in Europe. Disparate functions also agreed. In Sales, Marketing, Reimbursement and Medical, executives were united in their concern about pricing pressure and government / regulatory influence. Executives representing global headquarters and affiliates also had similar perspectives: Everyone in the pharmaceutical industry, it seems, feels squeezed by payers and government policy-makers / regulators.

Note that several executives in Europe expect new approaches to reimbursement by the UK's NICE and Germany's IQWiG to make the global pharmaceutical industry eventually adopt a less profitable, European commercial model. In the U.S., executives expect, and indeed fear, more government involvement.

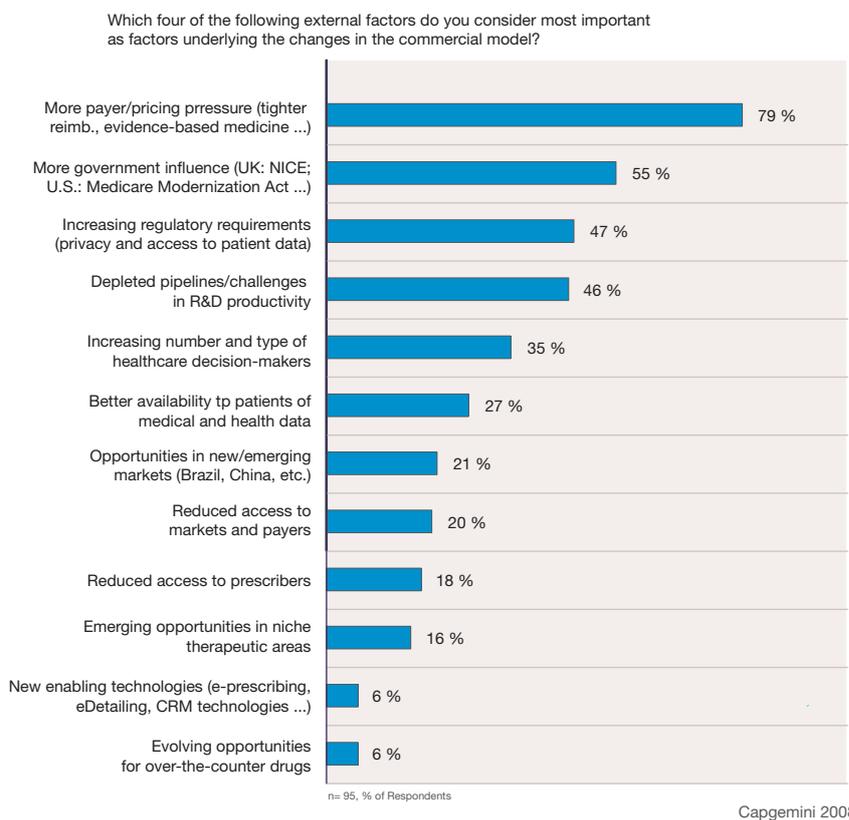
**Importance of stakeholders – and preparedness to deal with them**

We asked pharmaceutical executives to rate the importance of various stakeholders along with their industry's ability to address stakeholders' needs.

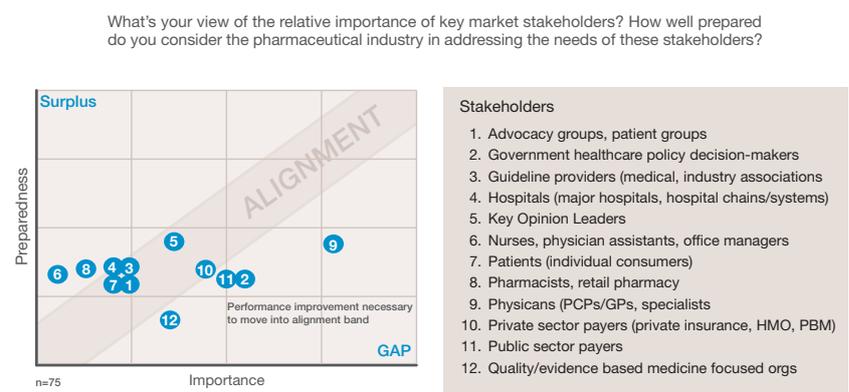
For some stakeholders, the attached level of importance coincided with executives' assessment of industry preparedness, indicating that pharmaceutical manufacturers were doing an adequate job with these stakeholders. Executives in particular felt that their strategies and resource allocation were appropriate in their relationships with patients, patient advocacy groups, hospitals, nurses, pharmacies, and major medical associations.

But our research also revealed that the executives feel unprepared to work with payers, governments, and quality organizations such as AHRQ that make recommendations – as well as with physicians.

**Chart 6 Study Participants' Ranking of Select Factors Driving Changes in the Commercial Model**



**Chart 7 Pharmaceutical Executives' View on Select Pharmaceutical Stakeholders**



Respondents were asked to distribute 100 points across the list of stakeholders twice, first indicating stakeholders' relative importance, subsequently indicating the industry's preparedness to address the needs of these stakeholders. Stakeholders are represented by numbers (see legend). Reference numbers displayed on the "Alignment Band" suggest the industry is sufficiently well prepared to meet the needs of the individual stakeholder, given the stakeholder's relative importance. Reference numbers displayed on the bottom-right suggest gaps in how well the industry is prepared, while numbers plotted in the "Surplus" corner (top-left) suggest a re-deployment of overly strong capabilities in order to use underlying resources more effectively.

Note that, while there was consensus about the industry's current unpreparedness to meet the needs of physicians, European respondents generally viewed the industry as insufficiently prepared to address the needs of government healthcare decision-makers. Most U.S. respondents viewed payers as the stakeholder group that most warrants more industry attention.

Note also that participants in our study expect some change over the next two to three years. Generally, the "physician gap" is expected to disappear during this timeframe – indicating that participants expect pharmaceutical companies to figure out how to re-engage physicians, and how to better collaborate with them. On the European side, participants expect the industry to face ever growing challenges in addressing the needs of government healthcare decision-makers; while in the U.S., participants are concerned about public sector payers.

► **Payers and physicians expect more collaboration**

**Case Study: Understanding Public Health better**

Capgemini is involved with numerous public health and non-governmental organizations to facilitate alternatives for better access to health and to Rx drug therapies. In addition, we work with pharmaceutical companies to re-design their specific go-to-market approaches in the area of publicly funded medicines.

What all these players seek to gain is more effective market interplay, e.g., through more targeted awareness and educational programs, high-value provider assistance, or faster access post approval.

In an era of increasing public health attention and concern, it is becoming more and more important, for pharmaceutical companies, to build solid public health capabilities complementing their traditional sales efforts.

**Payers' Perspective**

Throughout our surveys, interviews, panel discussions, and secondary research, one recurring theme was the complex relationship between pharmaceutical companies and payers. As discussed above, payers have gained in market influence and they have developed sophisticated analytics and pharmacy guidelines, both designed to influence their market.

In our round of interviews with half a dozen senior payer decision-makers in Europe and in the U.S., we learned that pharmaceutical manufacturers should spend more effort forging relationships with governments, public payers, patients, and retail pharmacies. Surprisingly, interviewees did not express the need for the pharmaceutical industry to collaborate more, or better, with private payers (even though several payer executives interviewed were actually based in the U.S. where private payers play an important role).

Overall, payers appeared cautious about collaboration with pharmaceutical manufacturers, although one interviewee volunteered the following list of potential opportunities:

- *Identify and treat patients early and engage in preventative measures*
- *Improve the overall health of the member population*
- *Bring cost-effective drugs to the market*
- *Improve outcomes of treatment*
- *Improve compliance*

### Physicians' View

A surprising finding gained from interviewing pharmaceutical executives was that physicians are dismissing payers as opponents, while looking to pharma for help.

As one physician panelist told us:

*"Pharma and physicians are really getting together more than pharma and payers."*

Another participant added:

*"Payers and physicians are diametrically opposed, they're never coming together. There's more animosity by the day."*

The relationship between physicians and pharmaceutical manufacturers is an ambiguous one. Although doctors want samples, they accuse representatives of cluttering up their offices. Doctors value the inventiveness of pharmaceutical manufacturers but they also believe that they invent diseases – thereby encouraging patients to seek medication to deal with problems (e.g., shyness or obesity) that might be better addressed through other means.

Payers are making physicians' practices harder. They impose caps and limitations on drug prescriptions. They also require physicians to obtain permission (or prior authorization) before administering drugs to patients or allowing prescriptions to be dispensed to patients. Reimbursement procedures for office-administered drugs are becoming increasingly cumbersome.

In an evolving healthcare system, patients can appear as victims. Physicians worry about patients who lack health coverage, or whose coverage is inadequate or highly bureaucratic. In the U.S., physicians are concerned that a two-tier payer system is emerging, so that not all patients are treated equal.

### Case Study: Scanning Managed Markets – Pricing, Reimbursement, and Access – for a Global Pharma Player

Payers are increasingly driving profound changes in the U.S. pharmaceutical market. With several products in late-stage clinical development, and close to launch, a global pharmaceutical company wanted to understand these changes, and leverage them proactively, so that new products could be launched in the most beneficial way in the evolving payer environment.

Capgemini helped the Managed Markets department in a multi-step approach:

First, the team carried out a broad scan of pricing, reimbursement, and access mechanisms utilized in various countries. These mechanisms were tested as to how they could be implemented in the U.S. healthcare environment, who would support and promote them, and what impact they would have on the pharmaceutical market. The results of this scan painted a clear picture of the potential future landscape, including relevant critical success factors for product launch and rapid uptake.

Subsequently, the team leveraged results of this global market scan to systematically "shape the product." By addressing unmet needs in the payer environment, the client was able to fill information gaps, fine-tune clinical trial definitions, define communication needs, etc.

As a result, the client gained significant benefits on multiple levels of the organization. Overall, the organization was educated on future pricing and reimbursement developments. Furthermore, several potential blockbuster drugs underwent systematic review with regards to payer needs, based on which key pricing and reimbursement priorities were defined. Finally, this project enabled the organization to define those processes and communication activities which could institutionalize these learnings for future products to be launched.

One physician described how a two-tier system affects providers' attitudes toward pharma:

*"Whether or not you like pharma reps depends to some degree on your patient base. Private: you can prescribe expensive drugs, so you like reps. Public: you can only prescribe cheap drugs and generics, therefore reps can't add much."*

Physicians believe that pharmaceutical companies can help in multiple ways, as one panelist pointed out:

- Supplying medical information
- Making unrestricted educational grants
- Navigating the payer paperwork labyrinth
- Providing samples and patient-access programs"

# IV. Re-Gaining Leadership through Customer Value Integration



As pharmaceutical profits have declined under the traditional business model, some industry players have started to adapt by exploring new market opportunities. A promising step appears to be integrating forward into the value chain, incorporating functions of the next market stakeholder, and thus becoming more able to reap additional revenues from further down the value chain. In practical terms, this means exercising more control over the distribution of products and services, and meeting more of the customers' needs.

There are many positive examples of such Forward Integration across industries:

- Airlines offer services traditionally performed by travel agencies (online booking)
- Information technology companies offer management consulting services
- Restaurants offer cookbooks, cooking classes, and similar products
- Retail banks provide consumer credit cards similar to those provided by independent card companies
- Automobile manufacturers offer financing services for customers, assuming a traditional role of banks

Business case calculations evaluating Forward Integration look at opportunities for reducing costs through economies of scale, mitigating risk, and acquiring proprietary distribution channels that might otherwise be used by competitors. Forward Integration can lead to greater overall market efficiency, particularly when a company is willing to invest in innovations that downstream stakeholders shy away from. Conversely, there are drawbacks: the development or acquisition of additional capabilities is expensive; maintaining more operations could mean less strategic flexibility, and downstream services often compete on price, forcing a unique low cost position.

► **Some pharmaceutical companies have already implemented Forward Integration**

Several pharmaceutical executives interviewed about successful efforts to develop new commercial models, mentioned cases of Forward Integration. For example, GSK launched a large clinical trial to see if an extended release version of a diabetes drug could help a subset of Alzheimer's patients. This is a case of integrating forward into the space of physicians who are forced to come up with other treatments as long as the desired extended release version is not available. Or, consider Roche CEO Franz Humer who reportedly said that personalized medicine will become increasingly important both to win approval and to demand high prices. This, again, can be seen as a case of Forward Integration into the physicians' domain.

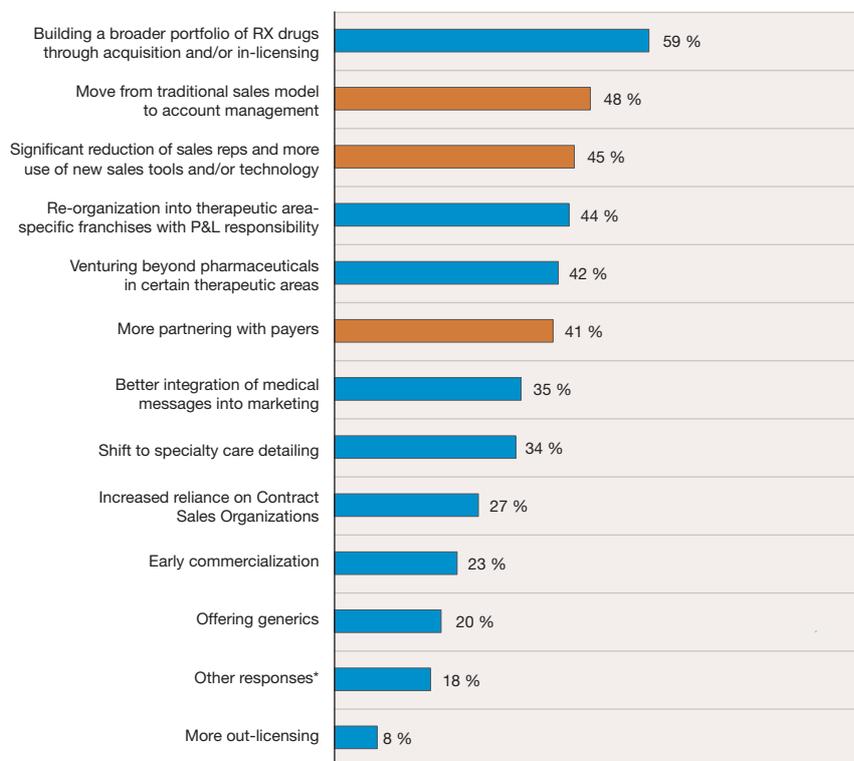
The most frequently cited examples of Forward Integration that emerged from our interviews fell into three main categories (chart 8):

- The move from the traditional sales model to account management:** Executives described retooling sales representatives into account managers and adopting a broader approach toward providers (such as providing in-depth medical information, managing inventories, coordinating payers, and designing, conducting, or analyzing outcome studies). Not only can these services benefit providers, they reduce manufacturer expenses for sales representatives and for physician education.
- Significant reduction of sales reps and increased use of sales tools and technology:** Rather than having scores of sales representatives waiting uselessly in physicians' offices or having multiple representatives touting different drugs from the same company to a single doctor, companies can implement new, customizable sales tools that provide more effective messages (e.g., online tools like Merck's Univadis).
- More partnering with payers:** Designing and running programs with payers such as employers, states, and managed care agencies can generate value by preventing disease, diagnosing it earlier, and making certain patients take drugs as prescribed. These programs can measurably reduce the cost and necessity of treating serious illness.

All of these strategies share a classic "win-win" mindset. They create value for pharmaceutical companies as well as for customers.

**Chart 8** Pharmaceutical Executives' Perspectives on Recent Successful Efforts to Implement a New Commercial Model

Which of the following efforts to develop a new commercial model have you seen being successfully implemented during the past few years?



n= 71, % of Respondents – multiple mentions possible

\*e-Marketing, e-Detailing, touch-pad tablets for physicians, customer segmentation, movement towards OTC and partnership

Examples of Forward Integration

Capgemini 2008

## Lessons within the Pharmaceutical Industry\*

### Genentech's Patient Support Center

Genentech began helping patients and physicians with reimbursement support as early as in 1997. The company launched a service called Single Point of Contact (SPoC), designed to provide reimbursement assistance for qualifying under-insured patients, while the Genentech Access to Care Foundation provided coverage for some uninsured patients (under certain conditions). Patients or physicians would contact SPoC by phone or Internet to get support and access support groups and foundations. SPoC representatives would match patients' insurance and treatment information with payer intelligence to provide the most efficient assistance possible. In 2002 alone, Genentech assisted nearly 5,000 patients at SPoC and provided nearly \$40 million worth of drugs through the Genentech Access to Care Foundation. The Genentech reimbursement group has evolved since its inception and today continues to provide centralized services under the newly launched Genentech Access Solutions brand.

### Pfizer's disease management program in Florida

From 2001 to 2005, Pfizer ran a program with the state of Florida to provide education and nursing services for Medicaid patients with chronic diseases in exchange for preferential treatment of Pfizer drugs on the Florida Medicaid formulary. Pfizer sent out over 400,000 mailings encouraging healthy behaviors; and nursing care managers had 65,000 in-person or telephone contacts with patients singled out for intense care, in the hope that such interaction would encourage patients to better manage their own health. The program continuously monitored the impact of interventions on patient behavior and cost metrics.

### Roche and personalized medicine

In 2006, Ventana Medical Systems received \$238 million in revenues for tools that help doctors analyze biopsies to diagnose cancer, a technology that might complement appropriate prescriptions of Roche's cancer drug Herceptin, which is most effective with elevated expression of the gene HER2.

As of late fall 2007, Roche is assessing whether to acquire Ventana. Ventana's technology helps doctors determine which drug to prescribe to individual patients based on a patient's genetic and other information. Such technology could avert potentially life-threatening side effects caused by prescribing the wrong medicine. For Roche, the acquisition would be an example of Forward Integration in the sense that additional needs of customers (physicians) would be met. These needs (diagnosis, for example by using Ventana's technology) precede the traditional physician need (prescribing medication) met by Roche (cancer product Herceptin).

## Lessons from Other Industries\*

### Financial services

**Example: One-stop shopping.** Banks used to be vertically organized such that each department was isolated from the other. This meant that if a customer accessing estate planning services at one bank wanted a loan, the customers would have to fill out additional paperwork for the additional service. Banks provided no convenience or other advantages to encourage customers to use the same bank for multiple services.

Merrill Lynch changed that paradigm by offering customers a range of services from the same contact point. It demonstrated that a customer-centric approach could increase value by boosting customer loyalty and satisfaction and so encourage customers to take on more of its offerings over a longer time. Similarly, First Direct, a subsidiary of HSBC, prospered as other banks were failing by adopting technology to share data across product lines. This created a way for service representatives to access accurate information on their customers in order to accommodate their needs and assess their satisfaction.

**Application to Pharma:** This “One-Stop Shop” service offering could be adopted by pharmaceutical companies to provide payers and account managers with a single point of contact for all products. Creating this technological infrastructure would help manufacturers track individual health plans and could be valuable when approaching such health plans with appropriate pricing and contracting options.

### Oil and gas industry

**Example: Differentiated value proposition:** Before 1995, Mobil tried to sell all products and services to all consumers, with little success. Two years later, Mobil North American Marketing and Refining had become the industry’s profit leader. What had changed was Mobil’s decision to offer premium customer segments premium service: convenience stores, self-payment mechanisms, etc. Mobil boosted revenues from products other than from gasoline. This made dealers and retailers less dependent on gasoline sales and allowed Mobil to capture a large profit share from the gasoline it supplied to dealers.

**Application to Pharma:** Pharmaceutical companies should put resources into selling the products and services customers are most likely to demand, and look for ways to capture gains from boosting customer revenues in premium non-drug sales, such as other health-related products and services (health / lifestyle management, “health booster” products – vitamin water, etc.).

### Aviation industry

**Example: Making customers collaborators.** In 2001, Boeing patented plans for the Sonic Cruiser, which would travel at close to the speed of sound, 20% faster than conventional aircraft. It was designed as a point-to-point aircraft that would carry only 250 people. But in 2002, Boeing asked its customers, global airline executives, to rank the factors they considered when buying an aircraft. In doing so Boeing learned that its customers favored fuel efficiency over capacity and speed and also that they did not believe that the touted speed advantages of the Sonic Cruiser would actually be realized. Boeing scrapped plans for the Cruiser and developed plans for the Dreamliner. In July 2007 before any new plane flew, this aircraft was the best-selling commercial jet ever through advanced sales. Its fuel efficiency allows the plane to fly 8,000 miles at a stretch, which means airlines can begin offering new non-stop routes.

**Application to Pharma:** Many pharma should not assume that they know what payers, patients, or physicians want. They should proactively work with these customers to develop attractive products and services going well beyond the traditional pharmaceutical business model.

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\*Researched using publicly available sources



► **Successful Forward Integration must consider the unique traits of the pharmaceutical industry**

There are plenty of lessons to be learned from other industries (see previous page). However, the pharmaceutical industry is different.

For example, the pharmaceutical marketplace is particularly complex, with several categories of customers and other stakeholders. For this reason Forward Integration for the pharmaceutical industry can mean moving toward any or all of these customers or stakeholders, like patients, physicians, payers, regulators, investigators, or “emerging stakeholders.” Not all forms of Forward Integration may be sustainable in the long term, however.

Today, several cases illustrate that many pharmaceutical companies are already creating new value in this complex market of customers and stakeholders. Meanwhile they are disintegrating on the back end with increased use of CROs and other vendors to manage traditional core aspects of R&D. This is where significant value is latent, and more pharmaceutical companies are realizing this fact. However, several non-pharma companies are already out in the market, defining innovative markets, creating demand, and capturing value, some of which pharma could compete for.

The challenge and opportunity for pharma players will be to build on their traditional competitive advantages in the evolving market:

- High barriers to entry
- Business cycle insensitivity
- Proprietary information (patents)
- Economies of scale (e.g., manufacturing)
- Access to capital (usually favorable cash position)

► **Customer Value Integration varies by type of customer or stakeholder**

The key to success for pharma in developing a new commercial model through Forward Integration will be to wisely evolve these strategic advantages (and create additional advantages) with all relevant customer and stakeholder groups.

In other words, pharma should identify value, generate value, and integrate such value into its own value chain – triggering a shift in the overall pharma value chain. Manufacturers have multiple options for doing so, due to the industry’s plurality of customers and variety of therapeutic areas.

These reasons are behind our decision to frame the term “Customer Value Integration” for what we envision as the new commercial model of pharma. In short, pharma needs to create new value, this value can be found on the customer side of the value chain, and this value needs to be integrated into the pharma value chain in a long-term sustainable way.

**I. Value Creation at the intersection of value chains of several players (manufacturers, payers, providers)**

Offering	Value created	Value primarily captured by ...
Reimbursement coaching and assistance for patients: <b>Health Advocates</b>	Independent insurance experts analyze insurance statements, coach on reimbursement terms, etc. Sponsored by employers (Home Depot, Bertelsmann, Earthlink, others) as a benefit to employees with the intention to facilitate easier and better prescription compliance by employees / patients.	Employees / patients, pharmaceutical companies, payers / employers
Health and Medical information for patients: <b>WebMD</b>	Independent online health and medical information for patients, partly financed by advertising	Patients, pharmaceutical companies
Product and other information for prescribing physicians: <b>Univadis</b> (physician website)	Health and medical information for physicians, provided by Merck & Co in several markets	Physicians, sponsor (Merck & Co)
Discounted medication for low income Americans: <b>TogetherRx</b>	Discounted branded prescription drugs, provided by several pharmaceutical companies in the U.S. as benefit associated with an exclusive "Together Rx Card" to qualifying low income patients	Low-income patients, sponsoring pharmaceutical companies

**II. Negative value and opportunities for value creation in pharma – physician / provider interaction**

**Efforts to interact with physicians should leverage information technology and rely on better physician segmentation**

In addition to recent efforts to cut sales forces and thereby reduce dead-weight loss, there remains tremendous opportunity for value creation in how pharma interacts with physicians.

Interaction	Current negative value	Opportunity for value-add
Detailing	Significant idle time of sales representatives	Opt-in information programs, physician portals
Commercial literature	Lack of interest by physicians	Opt-in information programs, physician portals
Sample inventory management	Inefficiencies due to inconsistent standards and lack of real-time use / supply tracking	Consistent, more efficient inventory management
Reimbursement management	Time-consuming effort by office staff (and physicians) to help patients understand and resolve reimbursement issues	Automated systems, online systems
Predominant targeting by prescription volume deciles and territory	Focus on individual physician or on coincidental characteristics (volume, territory)	Develop "intelligent targeting" based on aggregate understanding of sub-segments

### III. Negative value and opportunities for value creation in pharma – patient interaction

#### Patients' greater involvement in healthcare provides new opportunities to create additional value

With more and more patients demanding more and more medication and health-related services and products, there is tremendous opportunity to create new value in products themselves and in compliance and promotion.

Interaction	Current negative value	Opportunity for value-add
Patient input during drug development	Very little input means companies risk developing products with insufficient demand (various insulin inhalation devices)	Involve patients earlier in the development cycle ("early commercialization")
Health information	Patients do not know how to value information sources or lack access to them	Visibly "group" information sources in effective marketing channels to various patient segments; establish and develop health information brands
Lifestyle management (support and results tracking)	Patient demand for lifestyle help ("eat foods without animal fats") and longitudinal tracking of patient health status ("bad cholesterol decreased 10% over two months") is not sufficiently recognized, even as electronic health records abound	Facilitate development of consumer-friendly electronic platform, possibly leveraging current electronic medical records efforts
DTC advertising	DTC advertising efforts could actually be too broad and thereby become ineffective; or, consumer awareness created through DTC advertising could help competitors (bandwagon effect)	Continue to focus on well researched and targeted patient segments; optimize product value proposition communicated

### IV. Negative value and opportunities for value creation in pharma – payer interaction

#### Pharma companies can capture value from payers through enhanced collaboration

Payers have been very successful lately in creating value for themselves. Pharma should "re-patriate" some of that value by demonstrating that they are competent, trustworthy partners with unique capabilities.

Interaction	Current negative value	Opportunity for value-add
Payer input during Development	Very little input by payers or centralized drug evaluation agencies into development programs, trials, or cost effectiveness studies means manufacturers risk developing products which will ultimately face access hurdles from payers	Involve payers and agencies earlier in the development cycle ("early commercialization"), including in the definition of methods and definition of endpoints
Pricing	Payers minimally involved or are involved as private consultants creating potential conflicts	Co-develop and jointly refine healthcare / pharmaco-economic models over the course of the drug development process
Value demonstration	Pharmaco-economic models are too often qualitative, or not sufficiently sophisticated or credible for payers to buy in	Invest in comprehensive and solid pharmaco-economic models; develop world-class capabilities to present these credibly to payers, demonstrate value over time, and negotiate valuable returns with payers

► **Customer Value Integration will change how pharmaceutical companies are run**

The new commercial model will require competencies that many pharmaceutical companies today still need to develop. Companies must understand customers even better and know how end-to-end value is created by, and for, those stakeholders. Pharmaceutical companies need to segment stakeholder “markets” better, prioritize, attach value, and create segment-specific offerings – “Do we play in all segments?”, “Are niche segments of greater value to us than large segments?” Pharmaceutical companies need to strengthen their capabilities around market research, analytics, account management, patient relations, etc.

To gain the in-depth market understanding that is sufficiently granular and actionable, additional competencies should be built:

**Stakeholder Collaboration:** Companies should partner with a variety of customers to identify additional value. This means jointly examining opportunities of common interest in the marketplace and jointly developing these health-related and pharmaceutical products and services. This also means jointly identifying and removing barriers which would traditionally bog down innovation, and sharing risks and returns with customers or other stakeholders. And pharmaceutical companies should consider whether their capabilities are sufficient to exploit identified opportunities, and, if not, they should strengthen capabilities where this is deemed strategically necessary.

**Value Capture:** Companies must capture value from additional segments and specific stakeholders. This will mean negotiating gain-sharing agreements for long-term benefits and setting up joint ventures to test and incubate innovation. Once some traction has been gained in the market, companies should think about how to broaden distribution, and market to more or new customers.

**Franchise Protection:** Companies should learn to protect new franchises for the long run, to build on first mover advantage, to accelerate proprietary learning curves in order to leave potential competitors and imitators behind, and to leverage economies of scale to develop and sustain advantage.



# V. Integration and Collaboration with Stakeholders

**As stakeholders in the healthcare industry evolve, and some gain more power relative to pharmaceutical companies, the latter have an opportunity to position themselves as partners, not antagonists. This is not just a cosmetic change. It involves finding out what stakeholders value, and using that information to adapt and innovate both sales approaches and products and services themselves.**

## **Deeper, Fundamentally Different Relationships with Stakeholders**

This change also requires not only more sophisticated technology, but also a shift in mindset too. Pharmaceutical companies will have to focus on developing their brands in terms of products, services, lifecycles, patient experience, etc., not just in terms of their product portfolio. Doing so may require radical shifts, such as offering over certain aspects of diagnosis and treatment, or providing money-back guarantees for efficacy.

## **Pharmaceutical Companies and Payers: The Challenge of Complexity**

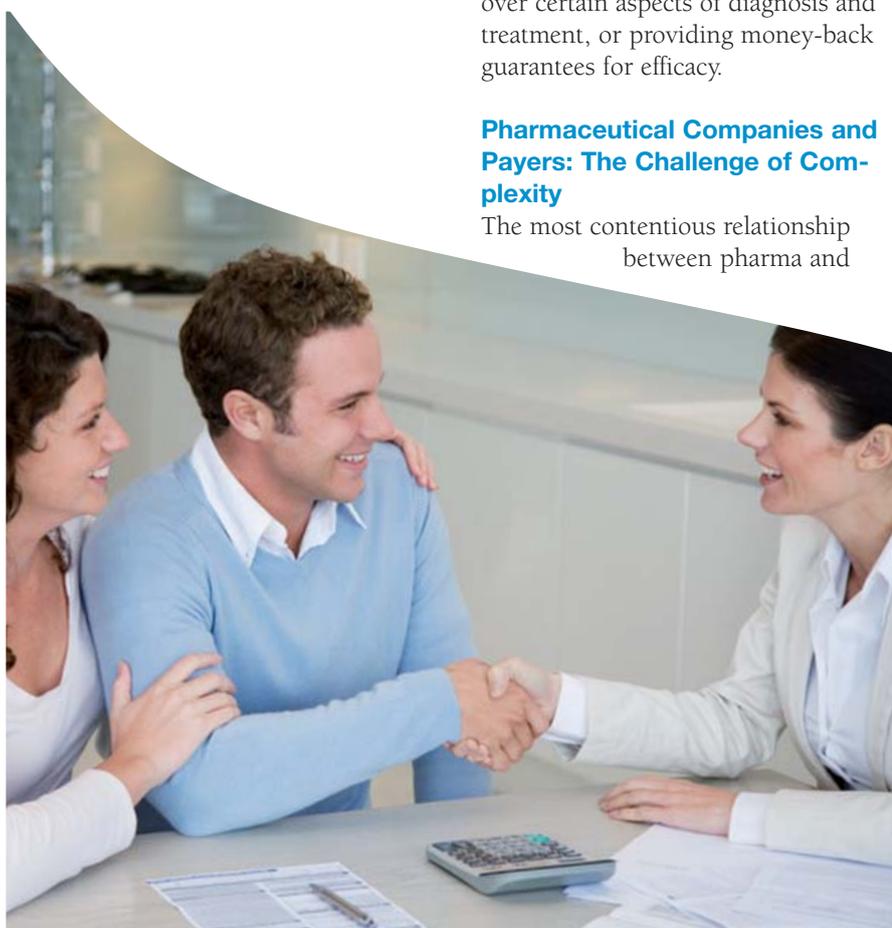
The most contentious relationship between pharma and

major stakeholder groups is the relationship with payers. As payer power has grown through the years, pharmaceutical companies have explored and tested various approaches to mitigate the restrictive effects of payer influence. There are numerous examples of success of individual therapies ultimately overcoming payer barriers, even gaining broad payer endorsement. Among those, there are some emerging themes that may have broad implication on how pharmaceutical companies can successfully engage payers into the future.

### **► Pharma is called to action**

To respond to increasing payer influence over increasing drug prices and utilization, pharma's formula for success may be refreshingly simple: Know your customer and respond accordingly.

Knowing your customer means, for one, understanding that provider and patient-level messaging is not what will compel payers to be supportive of new therapies, new indications, or new treatment algorithms. Then pharma can mobilize to meet this new reality. Simply put, there are messages that will not resonate with payers at all ("new mechanism of action", "novel, new treatment"), and those that will ("near-term aversion of more expensive medical procedures or complications", "better cost effectiveness and outcomes than existing therapies" – supported by clinically demonstrated models). There



are messages that tend to resonate with payers, including ones that address how this will affect the overall costs to the particular payer universe and how it will soon benefit the plan financially. In response, Pharma's call to action is to provide new and compelling messages (i.e., a "business case") to payers.

### ► Recognizing and embracing payer complexity

As the payer universe has evolved over the years, a complex system of interlocking entities and organizations has emerged beyond payers themselves. Many organizations have grown in sophistication and coordination, sharing results, and collaborating in initiatives, including those discussed earlier. They include standard-setting and guideline bodies, centralized or shared-use evaluation organizations, healthcare quality organizations, and specialized services organizations, including the pharmaceutical benefits managers in the U.S.

Many of these emerging participants continue to find new footing in macro therapeutic-choice decision-making. Here, one needs only to look at UK's NICE, Canada's Common Drug Review ("CDR"), and the emergence of Evidence-Based Practice Centers ("EPCs") in the U.S., and most notably the Drug Evaluation Review Project ("DERP"). While these bodies would not be confused with payers, their place in the reimbursement decision cycle is inescapable. Such organizations have become precursors to payers' formulary, appropriate use limitation, and reimbursement tier decision-making.

Pharmas need to recognize that payers have allies. Understanding and addressing the macrocosm in which payers operate will be key to future access and reimbursement success. To effectively cope with such complexity, pharmaceutical companies need to grow in their own sophistication.

### Innovation policy measures to facilitate healthcare market access of new technologies

**Several Millions of Euros were invested by the Department of Education and Research of a large European country in basic and applied research in the field of regenerative medicine. However, the few products which entered the markets in the last years did not generate significant sales. Therefore, the ministry wanted to identify hurdles for market access.**

Capgemini conducted an in-depth study of the different products and technologies on the market and in development, followed by an analysis of the industry structure, the market situation and especially the framework conditions for market approval and reimbursement. To overcome the identified hurdles and close the gaps in the current innovation policy, Capgemini made several recommendations for innovation policy measures.

As most of these proposed measures were placed in the areas of market approval and reimbursement, the client department joined forces with the Department of Health and asked Capgemini to facilitate a multi-stakeholder ASE-workshop with companies, scientists, clinics, payers, market approval bodies and institutions evaluating quality and efficiency of healthcare. In the ASE the different stakeholders were aligned (to some extent) and additional recommendations were made. In addition, pilot projects were designed to test the implementation of these recommendations.

As a result, the two government departments got a clear picture of the current market situation and the barriers for new technologies in entering the market. The government also accepted that drug approval regulations and cost-efficiency evaluations have to be adapted to these new technologies. Participating companies took the opportunity to get in contact with the different stakeholders and to position some of their products for the pilot projects resulting in a first cooperation with these public agencies.

Even today, the approach of many pharmaceutical companies to this connected network is fragmented and largely uncoordinated. Pharmas will need to develop connected responses to the expanding networks of players that payers have embraced.

Sales and marketing functions, managed care, government affairs, medical and scientific affairs, and corporate public relations groups will have to collaborate and coordinate on a new level to sustain and maintain the access and reimbursement levels once considered standard in the industry.

### ► Collaboration versus confrontation

The relationship between pharmas and payers has long been characterized as a zero-sum game, with one party winning at the expense of another. What's been missing in the pharma-payer relationship is true collaboration, notably in drug development. With

carefully-derived input and participation from payers, pharmas can develop and better characterize drugs that are truly impactful and can gain wider payer support.

Clearly, some leading pharmaceutical companies have become aware of this potential and are starting to explore various approaches. Merck's recent approach has been to invite payer executives to participate in its R&D outings and disease-state planning activities. Through this, Merck hopes to gain understanding on what really matters to payers, and better focus on developing differentiated therapies.

What seems clear is that the chess-game approach – opponent vs. opponent – cannot persist indefinitely for the successful research-based pharmaceutical firm. New approaches will be tried and tested, some refined, and some abandoned. Pharmas will be challenged to find new ways to coordinate, collaborate and integrate with payer organizations and their widening networks of alliances.

### **Pharmaceutical Companies and Physicians: The Promise of Closed-Loop Marketing**

The traditionally very close relationship between pharma and physicians has endured some strains. But physicians are still looking to pharmaceutical companies for help, and pharma continues to be dependent on physicians. It is an example of symbiosis at work. In the current context of increased payer control on physicians' activity and patient empowerment, pharma has the opportunity to redefine its relationship with physicians. To do so, pharma has to rethink the nature, the number and the quality of the interactions it has with physicians.

Traditional marketing campaigns have long gestation periods. They begin with market research to uncover needs, then analysis to find strategies to address those needs, planning to carry out those strategies, and finally, a year or so later, implementation. If one of those stages goes awry, companies often lack the flexibility or resources to make needed corrections. In an era of swiftly changing markets, a strategy defined before a major conference might not work after the conference.

At the same time, physicians are ever more reluctant to participate in the broad-based marketing approach favored by the pharmaceutical industry. Approaches used for one prescriber might not work for another.

Closed-loop marketing has the potential to accelerate the adjustment to market events while enabling a more customized go-to-market approach, if it is implemented correctly.

► **Marketing today must be fast and customized. Closed-loop marketing allows both**

In closed-loop marketing, every interaction with a customer becomes market research. The analysis comes from data generated within the company and its services. Call centers, e-marketing, speaker programs, journal publications, and other outreach activities generate feedback. Currently, this feedback represents greater variety, volume, detail, and frequency than most operations know how to deal with. Used properly, it results in a steady communication with marketing rather than wasteful event cycles. A sales representative can adjust to feedback that a physician provides at a speaker event or on the web site. Adjustments that can be made include customizing a message to individual physicians, changing an overall program (such as physician education), and



launching a new campaign based on earlier responses from physicians.

The rich feedback enables a new marketing approach. Closed-loop marketing does not presume that a launch can begin with the perfect message for each customer. Rather, this approach allows companies to create a prototype, quickly test it, and quickly adjust it. Intense testing can be avoided.

In closed-loop marketing, instead of in a few long marketing campaigns, marketing will be conducted in ever-accelerating feedback cycles. Marketing functions will become more aligned. Detailed information will provide more effective access to the customer, and better access will lead to more detailed information. This will feed into more prototype campaigns, with less effective ideas quickly weeded out. The return on investment for marketing can be better controlled, allowing resources to be matched with the efficiencies of different channels. Customers will think of pharmaceutical companies less as sellers and more as service providers with individualized messages and personalized offerings.

By making adjustments to information as it accumulates, pharmaceutical companies are both better poised to adapt quickly to a changing market and less likely to be caught unprepared by sudden market shifts.

#### ► Acting on feedback requires organizational change

Overall, closed-loop marketing allows faster reactions with fewer prototypes, but management cannot adopt the practice without adapting to it. Closed-loop marketing requires less reliance on upfront thinking in management suites, faster decisions at lower levels, and more flexibility throughout the organization.

New information-gathering technologies are already in place to access

#### Case Study: Business Model Transformation at Leading Global Pharmaceutical Company

A leading pharmaceutical company retained Capgemini to help its leadership team develop ideas and programs to give the company a competitive advantage in a changing market environment. Senior management believed the industry was facing fundamental changes and wanted to change the rules of the game across its entire business model.

Together with the client, Capgemini set up a Transformation Task Force and an ambitious work plan spanning five months. Program oversight and sponsorship was awarded by the highest level of the company, a fact that was instrumental in mobilizing the right talent, and obtaining the right management focus and dedication.

The teams were structured by stakeholders and included a physician team, a consumer team, a government team, an employer team and an outcomes team. Each team mobilized resources and contributors across the organization and carried out primary field research as well as secondary research and analysis to challenge the current thinking and models. Within the timeframe, these teams held 77 full-day workshops, engaged over 220 individuals in focus groups, carried out 113 “living-in-the-market” studies, consulted 108 experts, and held over 60 benchmarking discussions.

Its recommendations included tangible solutions to address the identified opportunities, a case for action and a proof-of concept plan along with a roll-out strategy. The outcome of this project included kicking-off a large number of pilot projects, namely in the area of how to address the specific needs of patient populations, addressing public market opportunities, rethinking the field force channel, and integrating commercial insights into development (early commercialization). The successful pilots were then rolled out into the broader organization.

information necessary for closed-loop marketing; what is missing is the mindset and the organizational focus to implement it. Technologies include tablet PCs, email, and websites. These can both collect the data for segmenting populations and customize interactions, according to segments. However, in order to use this information, organizations must be able to manage a large volume of information and rapidly analyze the information in order to understand its true meaning and implications. Organizations still need to grow their capability to incorporate rapidly new approaches and messages into the marketing cycle.

These capabilities can be classified as follows:

- Empowerment: Those with the appropriate information need the authority to act on it
- Feedback: Only the level of detail that can be applied effectively should be collected
- Analysis: This should be ongoing rather than event-driven; managers must carefully consider what information to use, and accept that not all feedback collected will be useful
- Marketing planning: Teams must adjust to faster information cycles and reactions. Decision-making authority should be delegated to allow customized sales aids, but these must still comply with regulations
- Execution: Those in sales must learn skills of marketing to collect and use information

Key challenges to successful implementation include compliance with legal and regulatory requirements, selecting the appropriate level of information to collect, avoiding “analysis paralysis,” and selecting which channels are most likely to benefit from the closed-loop marketing approach.

The change management needed to cope with the increased speed and flexibility across functions cuts across all of these challenges. Sales forces will need more specialized training while marketing materials must be prepared and assessed more quickly and collaboratively.

### ► Organizational change must be planned with care

Incorporating closed-loop marketing will mean changing organizational structures: building capabilities for deeper analysis, enabling bottom-up decision-making, and allowing more coordination across groups. As marketing messages change quickly, companies must adapt to support continuous copy review, or risk getting into trouble with regulatory authorities.

To implement closed-loop marketing, companies must think along several dimensions: brands, channels, and functions. Clearly the channels for connecting with customers as well as the appropriate level of investment in each channel will depend on the brand. Another factor that must be considered is pacing. Teams will vary in their capacity to plan pilots and roll out projects. Efforts must proceed slowly enough to incorporate feedback and fine-tune the approach, but quickly enough to sustain momentum.

The most successful implementations will first make sure that necessary information is being reliably filtered into the company. Next, the company can learn how best to act on that data. Ultimately, companies should shift toward managing programs as a cross-functional effort.

Even the early technology-heavy transition into closed-loop marketing requires departments and employees to step outside their usual areas of expertise. The technology environment must be able to integrate feedback across channels. This feedback will require different kinds of skills and resources to implement. The marketing and creative agencies, as well as copy review functions, must all be able to adapt to a faster-paced, data-driven environment.

### ► Closed-loop marketing will boost ROI

The benefits of such shifts can be profound: targeted messages will be more effective and defined more quickly. An improved ability to assess the return on investment for various channels and segments will allow companies to allocate their marketing resources more judiciously.

The benefits can be summarized in improved abilities in the following:

- Defining finer segments and more targeted messages
- Assessing ROI per channel and segment
- Applying accumulated knowledge on current products to future ones (predictive marketing)

Based on additional information, the most effective channel mix for each segment can be selected. For example, doctors unlikely to prescribe high volumes of a product can be switched to web-based communications, allowing one-on-one communication to be allocated more profitably. Different channels can be best matched to different purposes. Should samples or sample vouchers for a particular patient be provided by a personal visit, through web-ordering, or through an automated phone call? Should a request for information be addressed in person, through mail, through email, via a human phone call or an automated one? Getting the right answers to these questions means less money wasted in SG&A.

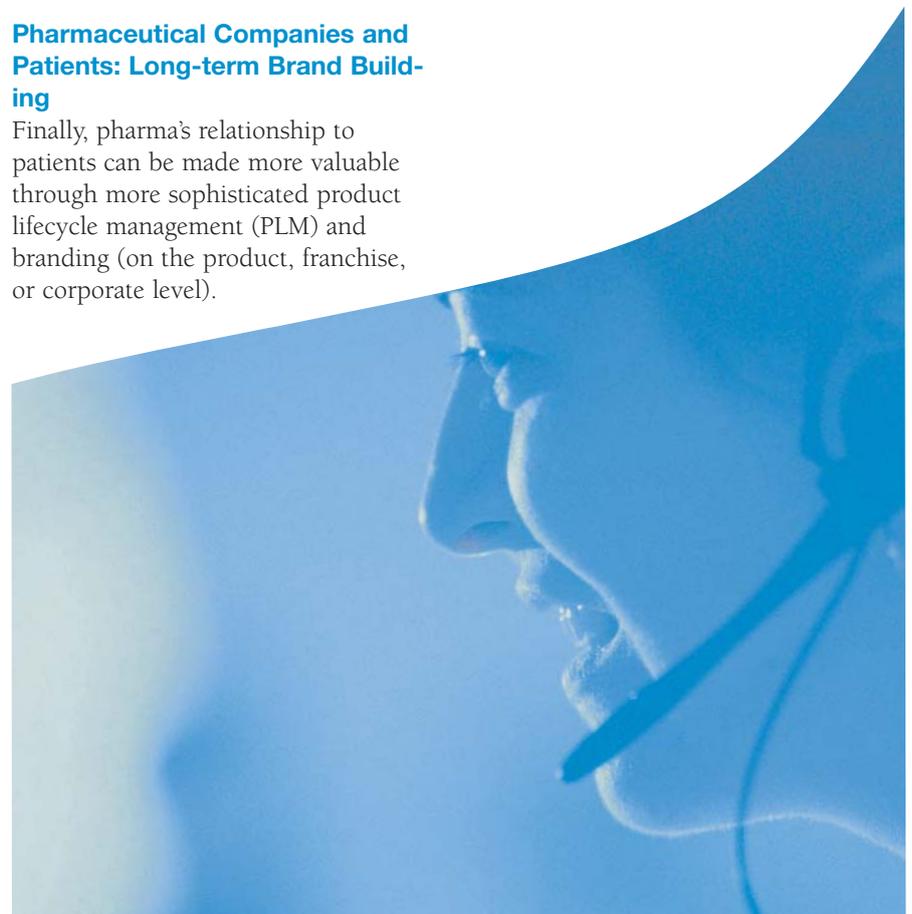
Most companies are still in the early stages of gathering the feedback to target messages. Once these techniques are established, they can enter the next phase, which allows greater return on investment: optimizing the marketing mix across channels. Eventually, they will be able to apply what they've learned on one product to an

integrated, predictive model. By worrying less about getting the perfect messages from the outset, companies will be able to create better messages over time.

Changes in the market will become more apparent, as will the ability to respond to them; resources will be optimally allocated across the different channels. Not only will this give companies greater control over marketing spend, their customers will be more satisfied with the messages they receive and how they receive them. Companies will be able to adapt quickly to changes in the marketplace and continue to influence the behavior of their customers. Thus, the end result of closed-loop marketing is that companies will be in a position to be more valuable to their customers – and in return circle and capture more value for themselves.

### Pharmaceutical Companies and Patients: Long-term Brand Building

Finally, pharma's relationship to patients can be made more valuable through more sophisticated product lifecycle management (PLM) and branding (on the product, franchise, or corporate level).



Akio Morita, the former CEO of Sony said: “A company should make its own products obsolete before the competition does.” But the pharmaceutical industry thinks of PLM in shortsighted terms, such as expanding an indication or formulation. PLM typically stops when a patent expires.

Pharma companies should take a much longer-term and holistic view of PLM. Indeed, PLM considerations should extend beyond an individual drug covered by a limited patent. They should begin to establish brands that customers recognize and that impart value to a product.

To do this, pharmaceutical companies must define their customers better. A customer is not just the individual (or organization) who pays. Rather, customers are those who have an interest in the product. And these interests vary greatly.

There are some powerful examples of branding in the pharmaceutical industry: Take Bayer’s 100 year-old aspirin, Novartis’ Voltaren or Pfizer’s Viagra, for example. Consumers are willing to pay more for Bayer’s aspirin because they trust the brand name. The next step is to establish a brand not so much at the level of the drug but at the level of the company. Initiatives like GSK’s 2006 announcement of a risk-pricing scheme for two of its products could be such a step. In this scheme, GSK is only reimbursed if its cancer drug meets certain efficacy criteria. This benefits payers, who only purchase effective treatments, but it can also benefit GSK, which can position itself as a supplier of reliable treatments. More systematic Phase IV studies would also demonstrate a genuine interest in providing only safe

and effective treatments and therefore win greater trust from skeptical stakeholders. However, this shift would require an increased focus on health outcomes. Pharmaceutical companies would need to innovate to boost the quality of treatment and reduce cost. This is a major shift from today’s practice, which relies on schemes to extract as much profit as possible from patent-protected drugs, even if better options arrive on the market.

► **Drug manufacturers should leverage their focus on treatments**

Pharmaceutical manufacturers should be able to claim higher prices for products that are better than those of the competition. Guarantees such as “we cure you or you get your money back” might also allow pharmaceutical companies to charge higher prices. Suppose pharmaceutical manufacturers could guarantee treatment at a given price, and then promote or supply various modes of treatment. Manufacturers could thereby learn more about treating a population, and treatment outcomes would improve. Eventually, a pharmaceutical manufacturer might be better able to care for a given type of patient at a lower cost than a payer. In such cases, the manufacturer would more efficiently offer treatment.

Obviously, there are many open questions that need to be addressed before such models become reality. Innovative healthcare solutions will enable the move towards pay-for-performance for pharmaceutical manufacturers, with payment based on health outcomes.

# Going the Next Step

Clearly, closer integration and better collaboration with stakeholders are only the first steps towards evolving the commercial model of a complex organization like a global pharmaceutical company. The toughest step is to make long-term investments that will extend significant value-generating operations beyond the traditional core of drug research, development, manufacturing, and marketing. While many pharmaceutical companies have started this process and expanded into

vaccines, medical devices, disease management, etc., they have generally stayed close to their core. The next consequential step will be to expand into telemedicine, health and wellness, health information management, or similar areas. Several non-pharma players are already in this space. It is up to pharmaceutical companies to assess the value of these emerging customer markets and seize the opportunity.

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## Study Team

### Directors:

#### Dr. Peter Barschdorff

Senior Manager, Life Sciences/  
Transformation Consulting  
Peter.Barschdorff@capgemini.com

#### Thomas Forissier

Senior Manager, Life Sciences/  
Transformation Consulting  
Thomas.Forissier@capgemini.com

### Contributors:

**Vandana Bahri, Germar Betz, Doug Moore, Hala Qanadilo, James Xiao**

### Research:

**Members and Graduates of the Strategic Research Group**

### Design and Production:

**Monika Hesse, Frank Schubert**

### Global Life Sciences Leadership Sponsors:

#### Omar Chane

Life Sciences, North America  
Omar.Chane@capgemini.com

#### Tim Dulle

Life Sciences Sector Head  
Great Britain  
Timothy.Dulley@capgemini.com

#### Günther Illert

Life Sciences Sector Head  
Central Europe  
Guenther.Illert@capgemini.com

#### Jean-Marc Neimetz

Life Sciences Sector Head  
North America  
JeanMarc.Neimetz@capgemini.com

### For questions regarding this research report please contact:

#### Monika Hesse

Life Sciences Marketing  
Central Europe  
+49 30 88 703 175  
Monika.Hesse@capgemini.com

#### Christine Schlumberger

Manager, Life Sciences/ Transformation Consulting, North America  
+1 (917) 547-9228  
Christine.Schlumberger@capgemini.com



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#### **Australia**

Capgemini  
Level 4  
50 Carrington Street  
Sydney NSW 2000  
Telephone: +61 2 9293 4000

#### **Austria**

Capgemini Consulting Österreich AG  
Lassallestraße 9b  
A-1020 Wien  
Telephone: +43 (0)1 211 63 0

#### **Belgium**

Capgemini Belgium N.V./S.A.  
Bessenveldstraat 19  
B-1831 Diegem  
Telephone: +32 (0)2 708 1111

#### **Canada**

Capgemini Canada  
200 University  
11th Floor  
Toronto, Ontario M5H 3C6  
Telephone: +1 416-365-4400

#### **China**

Capgemini China  
Unit 1101, AZIA Center  
1233 Lujiazui Ring Rd., Shanghai, PRC  
Post Code: 200120  
Telephone: +86-21-6105 3888

#### **Denmark**

Capgemini Danmark A/S  
Ørnegårdsvej 16  
2820 Gentofte  
Telephone: +45 70 11 22 00

#### **France**

Capgemini S.A.  
Place de l'Étoile  
11 rue de Tilsitt  
75017 Paris  
Telephone: +33 (0)1 47 54 50 00

#### **Germany**

Capgemini Deutschland GmbH  
Neues Kranzler Eck  
Kurfürstendamm 21  
D-10719 Berlin  
Telephone: +49 (0)30 88 703 0

#### **India**

Capgemini India  
SEP2-B3, Godrej Industries Complex  
Eastern Express Highway  
Vikhroli  
Mumbai 400079  
Telephone: +91 22 2518 7000

#### **Italy**

Capgemini Italia  
Via di Torre Spaccata 140  
00169 Roma  
Telephone: +39 06 231 901

#### **Ireland**

Capgemini Ireland Limited  
Hardwicke House  
Upper Hatch Street  
Dublin 2  
Telephone: +353 1 639 0100

#### **Netherlands**

Capgemini Nederland B.V.  
Papendorpseweg 100  
3528 BJ Utrecht  
P.O. Box 2575  
3500 GN Utrecht  
The Netherlands  
Telephone: +31 30 689 00 00

#### **Norway**

Capgemini  
Hoffsveien 1D, 0275 Oslo  
Mailing address:  
Pb. 475, Skøyen  
0214 Oslo  
Telephone: +47 2412 8000

#### **Poland**

Capgemini Polska Sp. z o.o.  
Al. Jana Pawła II 12  
00-124 Warsaw  
Telephone: + 48 (0)22 850 92 00

#### **Russia**

WTC World Trade Center Moscow p12,  
Krasnopresnenskaya, nab., Moscow  
123610, WTC, entr. 6, of. 1148  
Telephone: +7 (495) 258 24 39

#### **Spain**

Capgemini  
Anabel Segura, 14 – Edificio Cedro  
28108-Alcobendas (Madrid)  
Telephone: +34 91 657 70 00

#### **Sweden**

Capgemini Sweden  
Box 825  
Gustavslundsvägen 131  
161 24 Bromma  
Telephone: +46 (8) 5368 5000

#### **Switzerland**

Capgemini Schweiz AG  
Messeplatz 10/12  
CH-4058 Basel  
Telephone: +41 (0)61 692 08 42

#### **United Kingdom**

Capgemini UK  
Forge End,  
Woking,  
Surrey  
GU21 6DB  
Telephone: +44 (0)1483 764 764

#### **United States**

Capgemini U.S.  
623 Fifth Avenue  
33rd Floor  
New York, NY 10022  
Telephone: +1 (212) 314-8000