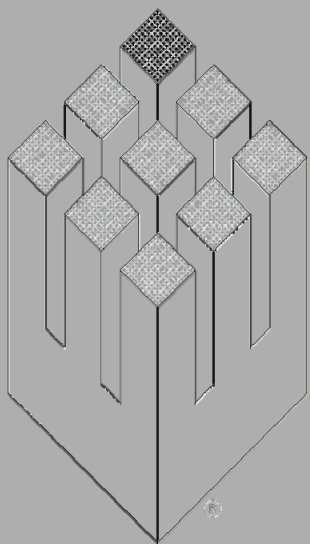


Big Pharma: How to Regain Success

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Successful companies and even entire industries all have a lifecycle, and all eventually reach a point where their business model approaches the end of that lifecycle and is no longer viable. Companies that are early in recognizing the shift and can execute the successor model effectively will typically become leaders in the next stage of the industry's development. Sometimes the transitions are incremental and gradual; more often, they involve discontinuity and dislocation. The outlines of the transition are always clear in retrospect, and most of our wisdom about such transitions derives from retrospective analysis. But what is the appropriate advice for companies that are in the middle of a transition – when the old model still appears to have life remaining and the new model is underdeveloped and unproven?

This is the situation facing the global pharmaceutical industry today. It's well known that pharma is going through a tough time. It's now fashionable among politicians, pundits, and journalists to criticize all the ways in which the industry's pursuit of profit conflicts with the healthcare needs of patients. The industry has had to bear greater scrutiny and skepticism from all its stakeholders than it has known for generations. The tangible impact has taken the form of patient lawsuits, governmental investigations, increasingly aggressive efforts of third-party payers to influence pricing and utilization of branded drugs, a more cautious approach to clinical evidence and new drug approval on the part of regulators, and new constraints on sales and marketing practices. These very serious challenges are reflected in the valuations that investors give pharmaceutical companies: as of March 2006, the Amex Pharmaceutical Index remained about 15% below the levels of March 2001. At the same time, it's fair to say that the reality beneath the headlines is much more positive. Given the rapid progress of medical science and the huge swaths of unmet medical need that remain, the opportunity for innovation is undiminished. Big pharma is still the natural champion for bringing safe and cost-effective therapies to the market on a global scale, and it continues to possess enormous competitive advantages in that role. At the end of the day, no one else can muster the critical competencies on the necessary scale to bring new medical therapies to market on a

consistent basis. To some extent, the industry has been unfairly maligned. It is a more convenient target of criticism than current dysfunctional systems for delivering and paying for medical care. It is also the victim of limited population understanding of the realities of medical science and healthcare economics – the inherent tradeoffs involved between innovation and

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short-term cost, between short-term cost of preventive care and long-term cost of acute and long-term care, and among the various combinations of efficacy and safety that all treatments (or non-treatments) involve.

On the basis of these underlying strengths, one could argue that the current problems are temporary and that the industry's primary imperative is to become more effective at public diplomacy. In our view, this conclusion is the wrong one for the industry to make. Healthcare delivery models are undergoing a sea of change. Rising costs will force us to change the way we look at healthcare. Over time, we will embrace the concept of a continuum of care that emphasizes prevention and more active engagement of patients in their own treatment not unlike the model adopted in the treatment of diabetes. Unfortunately, the pathway to get there will almost certainly involve more short-sighted and heavy-handed attempts to control costs. It is imperative for major pharmaceutical companies to become active participants in shaping public policy and the public's attitudes towards it. At the same time, there are very real problems with the current pharma business model. Leaders of pharma companies should seize this opportunity to conduct a fundamental self-examination and begin laying the foundation for their future.

Vulnerabilities of the current model

The dominant business model for the industry today is what we call the

Blockbuster model. In its simplest terms, the blockbuster model is about:

- ❑ focusing development investments on drugs that address large patient populations and appeal to a broader prescriber base;
- ❑ achieving high penetration of those markets through aggressive and expensive promotional activities to physicians and patients; and
- ❑ expanding market boundaries by pursuing new indications and broadening the prescriber base beyond the initially targeted specialists.

The remarkable success of some blockbuster products has reinforced each of these elements. At the same time, the inherent costs and risks of the model have encouraged company mergers on a mammoth scale and reinforced the barriers to entry into this elite club of global companies. All elements of the model continue to operate, but under increasing strain, due to some fundamental vulnerabilities.

The first vulnerability reflects the model's dependence on mass markets. The larger the target audience, the greater the likelihood that some segment of it will respond negatively to the product in question. Legal liability and societal backlash are likewise proportional to market size. In response to recent recalls of major products, the reaction of key stakeholders has been to emphasize safety as an overriding concern. The perception that big pharma has not been sufficiently sensitive to this issue has hurt the reputation of the industry. The concern has also translated into an escalating regulatory burden on the industry.

The second vulnerability surrounds significant costs in an increasingly cost-conscious market. The model is very expensive and requires three major cost drivers that continue to trend higher – discovery or acquisition of promising compounds, development through human trials, and marketing of approved drugs. Historically, companies have been able to recoup their investments and generate an attractive return by pricing their products based on efficacy

and safety, with only limited attention to the prices for competitive therapies or no therapy.

These escalating costs and associated prices are in direct conflict with a growing urgency in the United States and elsewhere in the developed world to control the accelerating cost of healthcare. Payers have some powerful tools at their disposal in this conflict. The greatest of these is the accumulation of existing therapies that are off patent or approaching patent expiration. As it has become easier to bring generic drugs to market, their overwhelming cost advantages have provided powerful incentives to payers and pharmacists to promote substitution. Even within the world of branded pharmaceuticals, the proliferation of compounds with similar properties makes it easier for payers to force greater price competition by granting preferential formulary status to selected brands. In a sense, the very advantage of many blockbuster products – that they address broad markets – has been turned against them.

The third vulnerability of the model is that it depends on mass messaging. In the past era of limited price sensitivity, competition was based on companies' ability to convey messages about features and benefits to physicians and patients. In this game reach and frequency were the critical metrics. As companies have increased the frequency of their messaging, the market has become saturated with physician detailing and DTC

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advertising. Beyond providing basic familiarity, the messages themselves tend to be low-value-added to their audiences. Not surprisingly, there is growing resistance – to the point of backlash – to this approach to marketing.

The market-driven business model

Inherent limitations of the current business model will lead to the emergence of a fundamentally new approach for the industry

that addresses the needs and interests of all the critical stakeholders. This market driven model rests on the following assumption. Successful companies of the future will determine what therapeutic areas they will 'own' which in turn will drive investments. Unlike the current approach, which is really *product* centric, the new model will be *patient* centric and take a *continuum of care vs. episodic care* approach. What this will mean is a core focus on prevention, diagnosis and treatment of the range of conditions within a therapeutic area, taking into account the needs of specific markets around the globe. This model can be characterized by its focus on strategic marketing, delivering real value to stakeholders, and innovation.

1. Stakeholder Value

The central imperative of the new model is delivering real value to critical stakeholders – payers, regulators, physicians, providers, and patients.

The FDA and other regulators remain a critical constituency. Companies need to find ways to accelerate time to market while reducing clinical trial costs and attaining optimal claims. Clinical and regulatory affairs groups will need to hone their capabilities for early and effective engagement of regulators to influence regulatory thinking, avoid surprises, and develop well-defined clinical strategies to ensure that the right studies are conducted in the right order to minimize delays and rework.

Payers are the newest powerful constituency. Pharmaceutical companies need to engage with governments, employers, and insurers to understand their needs, deliver solutions that address those needs, and frame the discussion over healthcare economics more advantageously. To accomplish this, several significant changes to the current process will be required. These include 1) healthcare economics considerations need to move to the front end of the product development and investment prioritization cycle, 2) clinical trials need to be structured to demonstrate compelling clinical and economic value in comparison with

available alternatives; and 3) the engagement of payer organizations need to be managed as a complex “selling” process.

Perhaps most importantly, companies need to change their go-to-market models – redefining the value delivered to physicians, providers, and patients while lowering costs. The heavy reliance on physician detailing is inconsistent with cost constraints and the need for more tailored and responsive dialogue. The role of personal promotion to physicians has not disappeared, but it requires greater sophistication, clinical knowledge, and business acumen than typical sales reps possess today in order to engage in the kind of meaningful conversations that physicians would truly value. Current technology also will play a role in getting information out to key constituents. Companies will need to define new approaches and develop new competencies to deliver value in ways that are cost-effective, convenient, and tailored to meet individual needs.

2. Strategic Marketing

One of the insidious characteristics of the blockbuster model is that it is inherently product-driven. Insiders at even the largest global pharmaceutical companies can name

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the blockbuster products that drive business strategy for the company. Because product revenues are so central to the companies' success, they also tend to be sales-driven cultures. All pharmaceutical companies invest in marketing capabilities, but these groups typically have too tactical a focus. In practice, marketing operates largely as a sales support organization.

In the market-driven model, strategic marketing drives all other activities and sales are repositioned as just one arm of the marketing mix. The central premise (and promise) of the model is that better

understanding of, and responsiveness to, the needs of all stakeholders will enable companies to better identify and dimension unmet medical need, determine therapeutic focus to drive disciplined portfolio investment decisions, deliver appropriate new therapies and ancillary services, and capture sufficient value for them. This promise can only be realized if companies invest in the capabilities of strategic marketing. Marketing that is truly strategic involves segmentation of markets based on characteristics that correlate with distinctive needs. It also requires a level of insight that goes well beyond the standard specialty- and decile-driven approaches in common use today.

3. Innovation Stewardship

Innovation remains the lifeblood of major pharmaceutical companies. Pharmaceutical innovation is inherently high-risk, expensive, part science, part art. But these attributes are magnified in the blockbuster model, which focuses on indications and molecules that have the revenue potential to sustain the commercial infrastructure of the company.

In the new model, companies will use marketing insights to determine therapeutic focus and drive disciplined portfolio investment decisions that reflect a more holistic view of product lifecycle value and the continuum of care. Once companies move to a market model with its more efficient and effective commercial arm, companies can focus more resources on R&D in those therapeutic areas that strategic marketing has determined to be the right direction for the company.

Along with this greater flexibility and focus, in a more cost-conscious environment, companies also need to extract more value out of their innovation activities. In their management of both early- and late-stage pipelines, they need to take a seamless, market-driven approach to selecting therapeutic targets. They also need to apply more flexible risk management and value capture strategies – including greater use of out-licensing and co-development – to derive the greatest expected value from the pipeline. In their management of products towards the end of their lifecycles, companies need to become more aggressive at pursuing exit strategies in order to focus

resources on what big pharma does best – bringing novel therapies to market.

Transitioning to the new model

If this analysis is logical and consistent with observable trends and our understanding of markets and human behavior, why haven't companies grasped it (yet) and turned it to their advantage? Partly, it's a function of human nature and organizational behavior; partly, it results from the dynamics of the pharma industry itself.

It is not easy to argue with success.

The greatest benefit of the recent difficulties is that they have shaken somewhat the

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natural confidence (and in some cases, arrogance) of an industry that has been extraordinarily successful for many years. As a result, pharma companies are starting to show greater receptivity to new perspectives that challenge some of the industry's core assumptions.

It is much harder to develop and execute a new business model than to make incremental improvements to an existing model. Transitioning to a new business model is like transitioning to a new technology platform. The current pharma model has been optimized for many years. Anyone who has spent time in the industry is familiar with the model and the various roles, processes, and metrics associated with it. Hundreds of thousands of people have spent decades perfecting the model. Even relatively recent phenomena like DTC marketing have gone through their entrepreneurial phases and the established approaches are now well-known.

In contrast, the market-driven model requires new capabilities and the organizational infrastructure to support

those capabilities. They will take time, effort, and investment to develop and perfect. The point of a market-driven approach is that there are discrete approaches for differentiated markets. Targeted approaches must be worked out for the sets of patients, practitioners, providers, and payers that define a market. While they will share many common features, their unique features must be identified, understood, and addressed.

Embarking on a new course always appears risky – at least until the current one is clearly no longer tenable. The tendency to conservatism is reinforced by the press of everyday operational challenges. In publicly-held companies it is further reinforced by the need to meet investors' expectations for short-term financial results.

It doesn't help the perceived risk of innovation that there are no reference points that are clearly compelling. We're sometimes asked who in the industry has employed the market-driven model. Some major pharmaceutical companies have applied some of the concepts successfully to certain markets and products, but to our knowledge no one has put all the pieces together on a significant scale. There are relevant experiences from other industries such as financial services, but they are accessible only to those executives who have the humility and the perspective to look outside the industry for inspiration and insight. And they require translation to be applicable to pharma.

There are powerful economic forces supporting the existing model. The current model didn't evolve by accident. The economics of the industry encourage a blockbuster product-driven mentality. The high cost and uncertainty of drug development limit the number of late-stage candidates, favoring those compounds that address larger markets and reinforcing the focus on maximizing revenues from the ones that are approved.

Given all these challenges, how can a company accelerate the transition and navigate it successfully? We've identified two principles that can drive progress and keep it manageable.

1. Develop and apply strategic marketing

Strategic marketing is the core competency of a market-driven pharmaceutical company, so the most appropriate place to start is to develop that capability.

In addition to investing in dedicated strategic marketing resources, companies need to embed their mindset and competencies in all critical functions and business units. The objective is not to create “think tanks” but rather to establish operationally focused roles that also have a strong external and strategic orientation.

2. Engage in active experimentation

The first application of the strategic marketing capability should be to identify a set of markets to develop and test new business model approaches. Companies should look for “early adopter” markets where the blockbuster model is most vulnerable and the advantages of the market-driven model are most compelling. They can then develop and execute integrated approaches tailored to the needs and characteristics of these markets. As with any new business development initiative, the twin goals should be to achieve success in the market and to maximize the learning that can be gained and leveraged from the experience. These franchises should be staffed with

The market-driven model requires new capabilities and organizational infrastructure to support those capabilities.


individuals who have demonstrated entrepreneurial competencies and strategic marketing capability.

At the end of the day, major pharmaceutical companies need to operate on a global scale. They cannot succeed at a market-driven business model if it means balkanizing their organizations into hundreds of disjointed and idiosyncratic pieces. The challenge is to design

Identify a set of markets to develop and test new business model approaches

scalable infrastructure that can be adapted to the needs of individual markets.

Conclusion

Profound market shifts tend not to be incremental. Pressures for change accumulate until they reach a tipping point. When that happens, business strategies that were recently viewed as prudent will quickly appear dangerously out of date. The pharmaceutical industry has already encountered some initial tipping points and others are bound to follow. We have entered a period when the prudent course requires innovation and risk-taking. Companies need to place a significant investment of resources and especially of management attention on defining and executing this new direction. 

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