

A background image of laboratory glassware. In the foreground, a large Erlenmeyer flask is filled with a vibrant blue liquid. To its right, a graduated cylinder contains a bright red liquid. In the background, a round-bottom flask holds a pinkish-purple liquid. The lighting is soft, creating highlights and shadows on the glass surfaces.

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Life Sciences & Health Care

The Changing Face of R&D in the Future Pharmaceutical Landscape

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The Changing Face of R&D in the Future Pharmaceutical Landscape

A Successful, Maturing Industry

The global pharmaceutical industry has generated strong sales and revenue growth for much of the second half of the twentieth century.

Over the 1996 - 2006 period, sales for U.S. firms, which increasingly dominate the global industry, rose from \$102 billion to \$276 billion while their R&D spending rose from \$17 billion to \$43 billion.^{1,2,3}

This growth has been driven by the development of mass market drugs, efficacious for large segments of the population and patent protected in developed country markets.

The industry has been characterized by waves of acquisitions and mergers, such that the typical big pharma firm, with about 35,000 employees in 1996, had grown to nearly 68,000 employees by 2006.^{1,4,5}

Measured over the past half century, the industry has been markedly successful in terms of financial results, innovation, performance or generated societal benefits.



Standardized Business Model Has Emerged

As the industry has grown, a standard business model has emerged as the larger firms increasingly pursued similar strategies emphasizing growth through the development of pharmaceutical blockbusters -- primarily small molecule drugs effective for large patient populations.

These industry players typically executed this blockbuster strategy by assembling massive internal capabilities and exploiting the scale economies possible on this asset base.

In a classic Catch-22 situation, the more effective companies were at developing such mass market blockbusters, the more effective they needed to be in developing even larger revenue replacements, as patents on existing products expired and markets were lost to generics.

While a more standard business model has emerged, the industry itself continues to change. Today, most large companies are globally positioned, place more emphasis on biologics, outsource significant portions of R&D, manufacturing and other corporate processes, and rely extensively on partnerships and alliances.

Yet the pharmaceutical industry increasingly has exhibited characteristics of a maturing industry. The larger companies have become more and more inflexible, both resistant to and incapable of, change. Product portfolios are aging as New Chemical Entity (NCE) output has continued to decline. Marketing and sales costs have escalated as incremental, not definitive, product differences become the primary competitive differentiator. Moreover, companies continue their blockbuster strategies, with order-of-magnitude increases in R&D spend, in spite of repeated failures.

The resistance to change, the apparent belief in one right strategy, the emergence of a standard business model, the growing focus on internal efficiencies rather than external threats, the continuing innovation decline, are symptomatic of a maturing industry -- and of an industry increasingly vulnerable to disruption by novel, new entrants.

This Business Model is Increasingly Unsatisfactory

Beginning in the late 1990s, some pharmaceutical company leaders began to caution that the industry's output of blockbuster New Molecular Entities (NMEs) (then about one per company per year) was significantly below the level (roughly three per year per company) needed to generate the revenue required to sustain the stock market valuations of pharmaceutical companies.

Closing this performance shortfall has increasingly dominated company agendas over the last ten years.

One approach emphasized massive expansion of R&D efforts. Over the past decade, R&D budgets have grown significantly. Vastly larger compound libraries have been assembled and screened for potential activity. International research capabilities have been established to access global talent pools. R&D alliances and joint ventures have been constructed to access and leverage any and all knowledge advances.

However, massive scale has not increased R&D productivity. FDA approvals of New Molecular Entities have at best remained steady, with only a handful of these approvals being truly innovative, first-in-class molecules. An analysis of current drug development pipelines suggests that the industry is nowhere close to replacing the \$65 billion⁶ worth of pharmaceuticals (25 percent ⁷ of U.S. ethical drug sales) going off patent in the next five years.

AstraZeneca, drawing on industry statistics showing annual growth in R&D spend and cost per NME of 9 percent and 18 percent of sales respectively, recently projected the total cost per NME to rise to \$2.3 billion by 2010.⁸ With unit costs at this level, we believe total industry R&D is significantly below that required to achieve annual output targets of three NMEs per company.

Another approach focused major efforts on increasing the efficiency of the R&D process. Virtually every pharmaceutical company has executed re-engineering programs to increase the speed and effectiveness of their R&D operations. Integrated knowledge management processes have been established to aggregate, correlate and assess the R&D information generated. Decision support mechanisms to continually realign R&D efforts based on potential risk/rewards are now common across the entire process. To date, there are few aspects of the R&D process which have not been re-engineered, restructured or realigned.

Yet, while individual companies have achieved performance improvements in different aspects of R&D, no significant industry-wide gain is evident.

A wide range of organizational initiatives directed at increasing the innovation in R&D activities have also been tried. Standalone R&D centers focused on specific therapeutic areas was one idea. Separating the unique research decision requirements from development was another. Devolving responsibility and authority for R&D results down the organization was another initiative. Significant outsourcing has been implemented to increase the flexibility and adaptability of the R&D process.

Results again have been mixed. Various companies have highlighted the improvements in their R&D efforts as a result of these initiatives. However, the results, in terms of financial performance, innovation or generated societal benefits for the industry in total, suggest little if any overall improvement in closing the R&D productivity gap noted by industry leaders in the 1990s.

The lack of sustained improvement suggests that continuing to increase R&D spend will not eliminate the shortfall in NME output, nor will increased process efficiencies or organizational restructuring. Indeed, the lack of results does suggest that the massive scale approach to small molecule R&D may be approaching exhaustion.



A Changing Landscape

A Fundamental Shift in the Industry's Operating Environment is Under Way

Today's pharmaceutical industry of Big Pharma companies and Big Bio, mid-sized players, and specialized service providers (CROs, etc.) has been shaped by the blockbuster strategy, as the strategy itself was shaped by the realities of the industry's operating landscape.

Historically, both diseases and affected patients were largely characterized by observable phenotype factors. By its very nature, segmentation by phenotype yielded large potential markets of affected patients exhibiting essentially the same physical conditions. The blockbuster strategy focused on developing drugs to exploit these large potential markets. The objective was one drug for large markets with typically 15 million-plus chronic patients and annual revenue potential of at least \$1 billion U.S.

Over time, this strategy has led to narrow product portfolios aligned against chronic disease markets, a relatively small number of truly innovative compounds, and a proliferation of drugs offering only incremental improvements.

This landscape is undergoing fundamental change.

Phenotyping of diseases is being replaced by an understanding of disease at the molecular level. Segmentation of patients based on observable characteristics is being replaced by segmentation based on genotype (with efficacy assessed by related biomarkers).

This change cannot be underestimated.

Technological advances are increasingly providing companies the opportunity to link treatments and efficacy to genetically homogeneous patient groups. While typical blockbuster efficacy rates range from 35 - 75 percent, genotyped market segments and biomarker-assessed responses promise treatments with significantly higher efficacy rates, possibly approaching 100 percent.^{9, 10}

The pharmaceutical industry's mass markets are fragmenting into genotype segments.

Like any industry, the pharmaceutical business is vulnerable to disruption if it fails to recognize and adapt to these changes. New players configured to exploit the new reality typically have operating efficiencies and product attributes, and provide customer benefits that simply cannot be matched by existing players organized to succeed in the old environment.

This Shift will Drive Major Changes in Existing Companies

Fragmentation of the industry's mass markets will drive disaggregation of many of the industry's existing players.

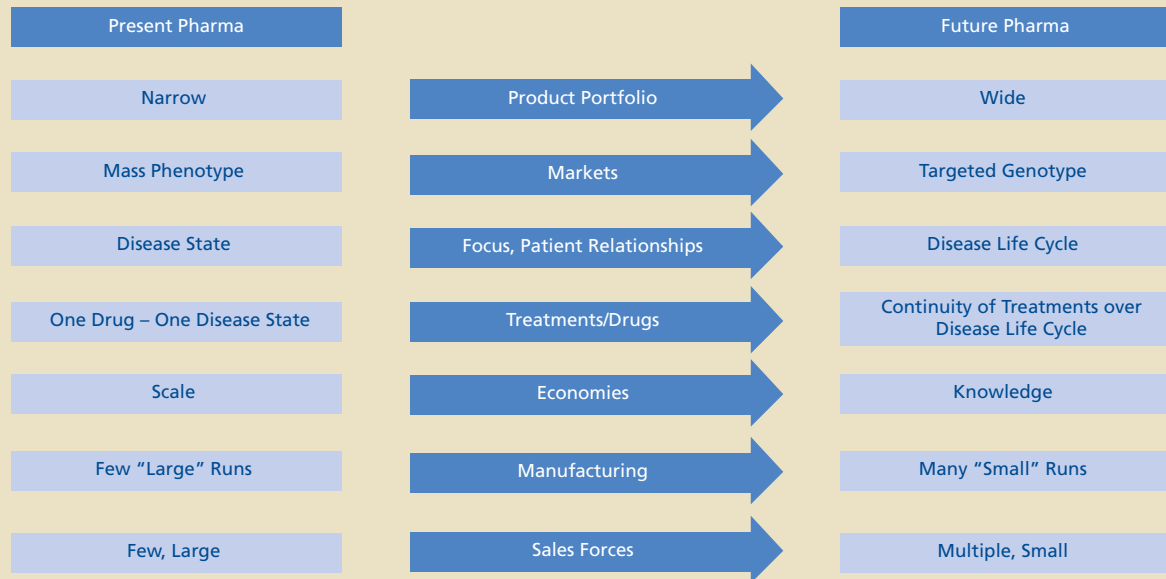
Serving more distinct market segments will, in turn, require more treatments. As such, product portfolios will evolve away from today's typical narrow product portfolio comprising a few, albeit financially successful, drugs for large markets, to a larger and wider portfolio of treatments for targeted segments. Personalized medicine – the one drug for one patient scenario – may well be the ultimate end point, although the complexity of such an environment is enormous.

While greater efficacy (flowing from genotyped clinical trials and biomarker-measured responses) has the potential to justify higher treatment prices, the smaller market segments will likely require longer patient relationships, perhaps over the disease life cycle (with treatments to match), to achieve revenue expectations. (See Exhibit 1.)

Growing understanding of diseases at the molecular level and increasing usage of genotyping and biomarkers to develop targeted treatments will likely expand the patient-disease matrix from a few phenotype paths to many genotyped paths. This, in turn, will significantly increase the complexity of the company's positioning and product decisions.

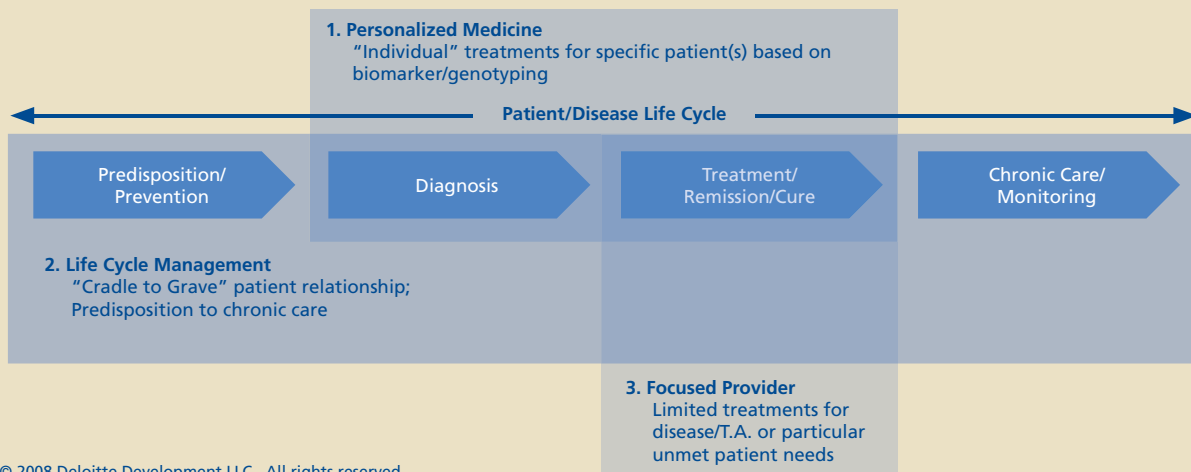
For example, how do the company's existing capabilities, products and resources align against the genotyped market segments of each disease/patient life cycle? (See Exhibit 2.) More importantly, what is the revenue potential of each segment? Should the company service only selected patient segments through all stages of the disease – a horizontal cut – or all segments in one stage of the disease – a vertical slice? Is the genotype segmentation of patients at one disease stage the same at other disease stages?

Exhibit 1. The industry's emerging landscape summarizes the major differences between the existing, and the emerging, industry environment.



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Exhibit 2. The Patient/Disease Life Cycle



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This change from few to many presents a direct challenge to existing industry players. Future financial success will require different capabilities, deployed in different ways. Companies have a choice as to how to participate in this emerging landscape. For example, current operations could be restructured to manage both existing and emerging businesses under the same corporate umbrella. Alternatively, some resources and capabilities could be spun out into a new, arms-length company configured explicitly for the new environment. In either case, the new operations could be established as tangible, vertically integrated structures or virtual organizations with the company as a participant in, or leader of, a patient-health care network.

Two capabilities will be critical to financial success. As enduring treatment monopolies are more likely from targeted, high-efficacy treatments for similar genotypes, first-to-market will be even more critical than today. Second, with smaller markets for each particular

treatment (due to genotype market segmentation), establishing and maintaining true relationships with the patients, and the health care system supporting them, will be essential to maximizing patient and company benefits.

For Big Pharmas, the major problem will be managing the transition to an organization of many smaller companies focused either vertically against a single disease state for all genotype patient segments or horizontally against all disease states for a particular genotype patient segment. With targeted treatments for specific patient genotypes (and much higher efficacy), we expect that the number of treatment alternatives, specifically the current plethora of incrementally better me-too's, for any particular disease state and genotype patient segments will decrease. As any company is unlikely to develop all the treatments to cover all genotype segments across the disease life cycle, deal making, alliances and collaborations for product acquisition will be of even more importance than today.

While Big Pharma has on paper much of the capability needed to service patients in this new landscape, the restructuring task is enormous, and the management of the new structure is different and significantly more complex than even today's challenges.

Big Bios, smaller than Big Pharma, have less of the resources needed for financial success in the new landscape, but do have the freedom to assemble the required new capabilities on a greenfield basis. Obviously, their biological-based R&D operations are an advantage given the trend toward more large molecule R&D, although these too will have to be restructured to reflect the genotyping-biomarker changes to drug development.

The size and momentum inherent in large drug development programs does, however, expose Big Pharma to an increased obsolescence risk. New entrants could focus on treatments for a narrower genotyped market segment, and if successful, effectively render Big Pharma's drug development programs, focused on broad phenotype markets, uneconomic.

Big Pharma companies do possess one potentially valuable and proprietary asset to exploit in the new landscape. Each owns a portfolio of small molecule failures – potential drugs with good safety profiles who demonstrated no significant efficacy in phenotype patient samples. Remaining patent protection on these compounds varies but retesting against genotyped trial samples with relevant biomarkers could provide a substantial kick start to entry in the new landscape.

Industry service providers (CROs, CResOs, CMOs, etc.), face the same transition problem as Big Pharma. At present, their resources are primarily aligned to support large-scale, small molecule R&D and their revenue largely determined by volume (e.g., number of trial subjects, number of analyses, manufacturing runs). With industry R&D shifting toward large molecules, their current business will likely slow, competition increase among existing providers and margins decline. At the same time, there will be increased demand for services to support large molecule R&D, to reevaluate prior small molecule failures, and to support more numerous but smaller-scale R&D programs directed at specific patient-disease states and genotypes. However, while the demand to support the emerging business will grow, the application of genotyping and biomarkers likely means that the real volume of some services will be smaller overall (i.e., fewer trial subjects, shorter trials, less analyses).

A major issue for service providers is whether or not to attempt to become the dominant provider of certain new services that will be required in the emerging landscape. While genotyping and biomarker application are two obvious areas, other service opportunities exist, for example, in the expanded relationship management task, in the more complex logistics and distribution of new treatments, or in providing effective sales coverage of much smaller markets and for smaller players.

Mid-sized players, both pharmas and biotechs, face a difficult situation in the emerging landscape. They have many of the transition problems of Big Pharma without their financial capacity or substantial operational capabilities. They have insufficient resources to position themselves to service an entire vertical or horizontal market segment. As targeted treatments for genotyped market segments eat into their existing markets, their revenue streams likely will decline. Without the strength of the bigger firms, they have limited ability to drive the formation of treatment networks. On the other hand, the smaller R&D programs likely with the application of genotyped patient samples and biomarker-assessed efficacy mean a lower market entry hurdle into new disease areas.

Overall, mid-sized firms with small, narrower portfolios are highly vulnerable to fragmentation of their phenotype markets. Mid-sized firms have two choices depending on the merits of their current portfolio. Companies with weak portfolios, containing few, if any, first-line treatments, face the prospect of a precipitous revenue drop as current first-line treatments are re-evaluated and aligned more closely with genotyped, high-response patients. For these mid-sized companies, business as usual likely means a speedy demise. Their only realistic strategic option is to identify treatment gaps in the new landscape and aggressively move to develop appropriate treatments in a similar fashion to entirely new entrants.

Mid-sized companies with some first-line treatments do have value to those emerging networks focused around patient-disease life cycles. The network's product portfolio and extended patient relationships do provide greater competitive strength than that available as a stand-alone player.

The likely scenario for many mid-sized firms will be integration into a network managed by a Big Pharma (or a NewPharmaCo), where they would provide some components of the full treatment coverage offered for the vertical or horizontal market segment.

In summary, while many of the existing players have the capabilities needed in the new landscape, and will, of necessity, have to evolve to survive in the restructured environment, pharma companies have not demonstrated great ability to rapidly adapt to external change. As such, they are particularly vulnerable to new entrants with organizations designed specifically for the new landscape.

We believe it likely that some existing Big Pharmas, facing significant patent expiration issues and low NCE output, will fund NewPharmaCo startups to aggressively compete in the new environment while they themselves concentrate on their existing business.



The Future R&D Model

Significant New Players – NewPharmaCos – Will Emerge

Every industry disruption is characterized by the demise of current players who fail to adapt and the appearance of highly competitive new entrants.

We expect the disruption of the pharmaceutical industry to unfold in a similar fashion, and anticipate the emergence of NewPharmaCos specifically configured to be financially successful in the new environment. These new entrants could be spinoffs from existing players or entirely new entities.

The business opportunities created by the disruption are too attractive to ignore. Virtually every currently licensed product is vulnerable to replacement by targeted treatments for specific genotypes. Existing companies have a vested interest in not destroying their current market positions. New entrants have no such qualms about attacking existing market-phenotype product combinations.

These NewPharmaCos will embody many of the characteristics highlighted in Exhibit 1. They will focus on genotyped market segments. They will concentrate on assembling treatment portfolios that span the patient/disease life cycle. Their organizations will be scalable with variable, not fixed, cost and capacity structures. They will embody highly effective practices in innovation.

A critical determinant of financial success for these new entrants will be ownership of the genotype–biomarker combination that identifies high-efficacy treatments for a particular patient–disease state. Whether determined upfront, as in the case of Genentech’s Herceptin® or Imclone’s Erbitux®, or retroactively in the case of Sanofi’s Clpidogrel, this knowledge permits the evaluation of current and potential products to identify and fill possible treatment gaps.

Priority disruption targets for this genotype-biomarker search are those current blockbusters with lower efficacy rates, perhaps 50 percent and below. Half the market is not being served at all. The other half likely has a number of alternative treatments of varying efficacy. With existing players unlikely to disrupt the status quo, new entrants can be first movers in the development of more efficacious targeted treatments. More effective drugs, in turn, provide the potential

for significantly higher patient compliance arising from the positive experience of an effective treatment. The price premium for therapies with a high probability of therapeutic success could also be substantial.

We anticipate these NewPharmCos will be organized upfront to enable rapid adaptation to any future changes in the industry’s operating environment. While the existing industry players have made significant efforts to increase their flexibility and adaptability through alliances and outsourcing, they retain substantial inertia due to their size and complexity.

In contrast, we foresee new entrants establishing themselves first as virtual organizations serving specific patient-disease state markets. The genotype-biomarker knowledge provides the opportunity to identify or develop high-efficacy treatments to monopolize such segments. We expect that new entrants will expand outward from these initial positions to establish and manage disease-specific networks. Such networks would consist of virtual and real companies, patients, and elements of the health care system covering the disease life cycle.

Managing such a network means orchestrating the network’s capacity and capabilities to sustain dominance of selected patient-disease life cycles. Building consensus, maintaining cooperation, moderating risk and allocating rewards are all critical, and new, skills that will be required by NewPharmaCos and existing companies that decide to play in this area.

Creating networks and treatments for the patient-disease life cycle means establishing a relationship with each patient and with the entire patient group. Physically located components of the health care system deal with specific patients, not with geographically distributed patient populations. Only NewPharmaCos with their virtual structure and the nature of their interaction with the patients can deal with the entire patient population as it moves through sequential disease states. This, in turn, means that NewPharmaCos will require the often maligned capability of relationship management if the network is to benefit both the patient group and the network participants.

New entrants will need the R&D capability to deal both with the development of genotype-biomarker packages and to develop new molecules, large and small. However, we again anticipate this R&D capability to be virtual, comprising a number of separate entities assembled in an R&D network, affording significant flexibility and risk management. We expect NewPharmaCos' R&D priorities to be twofold: First, product development and acquisition for those market segments now identified as unserved due to the need for genotype market segmentation. Such product development would include genotype-biomarker packages for efficacy evaluation. Second, similar to Big Pharma's jump start, re-evaluation of those failed, off-patent, drugs with good safety profiles to assess genotype-specific efficacy.

NewPharmaCos' threat to existing players is substantial. While existing companies are locked into long-term, large, complex R&D programs, and restructuring their organizations for the new environment, NewPharmaCos will be conducting themselves and their R&D in the new fashion from day one. They will be faster, more agile and significantly leaner than existing players. They have the potential to win the new competitive battle in the emerging landscape before the existing players can adapt.

R&D Realignment is Needed to be Financially Successful in the New Landscape

Historically, R&D has been structured to support the blockbuster strategy. This meant large R&D programs, standardized processes, high-throughput, factory-type operations, and efficacy measured by the statistical significance of clinical endpoints.

Competition in the new environment, focused on genotyped patient populations and disease life cycles, demands a different R&D approach incorporating;

- R&D **strategies** that support the assembly of treatment portfolios for the entire disease life cycle
- Virtual, disease-specific R&D **networks**
- Virtual R&D **processes** with significant outsourcing to maximize flexibility and manage development risk
- Focused R&D **programs** based on genotyped patients/subjects and biomarkers
- Partnering and collaborative **ventures** to access disease knowledge communities.

With growing understanding of diseases at the molecular level, and treatments now emerging which affect the disease's progression rather than alleviating symptoms, it will no longer be reasonable to treat a patient in one disease state and ignore the treatment's implications for the patient's next disease state. Given the focus on patient life cycle treatments, the level of the patient's benefits from the relationship will be directly dependent on evaluating the impact of different treatment regimes.

This will have a direct impact on R&D efforts. We expect R&D programs to have to consider the patient-disease progression possible through different treatment regimes. This, in turn, implies a much more iterative R&D effort where actual patient results, post-approval (phase IV type information), and competitor product development efforts feed directly back into an R&D process continually reassessing both treatment and development options.

With the increasing efforts linking genotype, biomarkers and disease states, we expect the R&D process itself to both shorten and incorporate significantly more feedback loops not only between development and research but within development itself. These efforts over time will continue to blur the line between research and development. Overall, we would expect development timelines to shorten substantially with smaller trials of potentially high responding subjects, and efficacy assessments from biomarkers.

Going forward, we expect the traditional line between biotech and pharma companies will become irrelevant. Pharma companies are increasingly investing in and collaborating with all types of biotech players. The explosion of genetic knowledge and the implications for disease treatments means that this collaboration will only intensify. Again, we expect this trend to be reflected in R&D efforts, resulting in treatment portfolios for a particular disease life cycle containing both small molecule drugs and biologics applied to different patient-disease states.

Industry Maturity and Rebirth

Today's industry of Big Pharma and Bio, blockbusters, factory-scale R&D, and massive detail sales forces is maturing. The resistance to change, the similarity in corporate strategy and structure, the intense focus on internal efficiencies and productivity, and the ongoing fall in innovation exemplify this maturity.

Technological change is disrupting this mature status quo.

Genotyping, biomarkers, and molecular-level disease understanding, all emanating from the continuing advances in genetics, are fragmenting the industry's traditional mass markets, and forcing the redefinition of diseases.

These developments will drive change in all aspects of the industry.

With this industry disruption, some existing players will fade away, some will change and adapt, and some new entrants will rise to dominant positions.

Lessons from other disrupted industries highlight both the stark facts and choices facing existing players in the pharmaceutical industry:

First, such disruptions are unstoppable.

Second, the choice for existing players is clearly control or be controlled – rapidly adapt to the new environment and influence the emerging competitive arena or let new entrants determine your future.

New Entrants – the NewPharmaCos – from whatever source are the critical threat. In their self interest, they accelerate the pace of disruption, further marginalizing existing players too slow to change. They will aggressively drive the transition toward the end point of personalized medicine as the attractive replacement for the perceived impersonal and monolithic pharmaceutical companies of today.

Research and development will continue to be the industry's core value generator. However, it is R&D configured for smaller genotyped market segments, creating targeted treatments, focusing on the patient over the disease life cycle, and working intimately with the other entities in the health care network, both competitors and collaborators. It will be a virtual R&D process in a network of disease-specific organizations and patient groups.

Adapting to the new landscape will not be easy for existing pharmaceutical companies. They are large organizations, staffed by individuals with a vested interest in preserving the status quo, even if such preservation leads to extinction. These companies have massive internal asset bases, focused on specific objectives, operated at high utilization levels and possessing considerable resistance to directional change. However, changing to compete in the new landscape is a survival necessity, not an option.

Companies that have financial success as the current business archetype evolves into the newpharma model will be those that define the emerging paradigm. Those that merely follow the trend can still survive, but only with some luck. Those that hesitate, or ignore the gathering storm, will most likely be lost.



References

- ¹ PAREXEL's Bio/Pharmaceutical R&D Statistical Sourcebook 2006/2007
- ² PhRMA Web site: www.phrma.org
- ³ S&P Pharmaceutical Industry Guides
- ⁴ Fortune 500 Archives web site: 1996 company information
- ⁵ OneSource Global Business Database
- ⁶ 2006 Annual Reports for AstraZenca, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Merck, Pfizer, Sanofi Aventis, and Wyeth
- ⁷ IMS Health: U.S. 2006 Sales
- ⁸ R&D Leaders' Forum Conference (March 2007). Presentation by Dr. Wayne Rosenkrans, Scientific and Medical Director, AstraZeneca, "Demonstrating the Value of Pharmaceuticals."
- ⁹ R&D Leader's Forum Conference (March 2007). Workshop discussion on "Developing Robust Decision Criteria for the Development and Use of Biomarkers: Learning From Regulatory and Industry Experiences to Date."
- ¹⁰ "Targeted Therapies: Navigating the Business Challenges of Personalized Medicines." Produced by the Deloitte Center for Health Solutions and Deloitte Consulting LLP, 2007.

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