

Pharma 2010: The Threshold of Innovation



This paper is part of IBM Business Consulting Services' on-going commitment to forward-looking industry and business points of view, and our aim to help companies and industries Transform Futures. It follows up on the work we published in the "Pharma 2005" series.

Pharma 2010: The Threshold of Innovation

In 2010, the pharmaceutical industry (Pharma) will not only make white powders; it will sell a variety of products and therapeutic healthcare packages that include diagnostic tests, drugs and monitoring devices and mechanisms, as well as a wide range of services to support patients. Companies that learn how to make "targeted treatment solutions," as we call them, will deliver bigger shareholder returns than they have ever delivered before. This is what our vision of the future looks like.

Discovery and Development

Drug discovery and development will be underpinned by an understanding of how different diseases function both at a molecular level and as part of a biological system. The molecular sciences will enable the industry to define diseases much more accurately – and to create a collection of treatments and services for patients with specific disease subtypes, rather than making one-size-fits-all drugs for patients with similar symptoms but essentially different diseases.

Many of these new medicines will be based on biology rather than chemistry, because biologics are typically less toxic than chemical entities and behave more predictably. They will be made using biological methods of discovery and research, which are easier and faster than traditional methods. And they will be available in a variety of formulations that patients find convenient, rather than having to be delivered by injection.

Modeling, simulation and high-performance computing will play a vital role in the way such medicines are discovered and developed. They will enable the industry to model how drugs act in whole body systems, organs and at a sub-cellular level; to design accurate trials; and to conduct adaptive trials, where information acquired during a particular trial is used to modify the course of the same trial without compromising its statistical validity.

Promising new drugs will first be tested in man during late-stage discovery, to prove their safety and efficacy. They will be tested still further in Phase II trials and submitted to the regulators for conditional approval. They will then be launched on the market and subjected to additional "in-life testing," using a variety of remote monitoring devices that exploit advances in bandwidth, networking, mobile telecoms, radio frequency technologies and miniaturization – thereby obviating the need to expose patients to placebos or dosing levels that are pharmacologically ineffective.

Collectively, these changes will blur the boundaries between discovery, development and the marketplace – creating a fully integrated model. They will also massively reduce the time and cost of making new drugs. In 2010, the discovery and development process will take half as long as it does now, and costs per drug will fall to a quarter of the current average.

Regulation

Pharma companies will initiate contact with the regulatory authorities regarding the development of a particular treatment while it is still in the early stages of discovery. They will submit clinical data to the regulators on an ongoing automated basis via rolling dossiers. And they will work much more closely in partnership with the regulators throughout the entire discovery and development process.

The very basis on which the regulators grant permission to sell a drug will also change. The traditional one-off endorsement will be replaced by continuous evaluation. The right to market a drug will be granted and re-confirmed subject to regular reviews of its safety and efficacy – reviews that are even more stringent than the checks involved in adverse-event reporting.

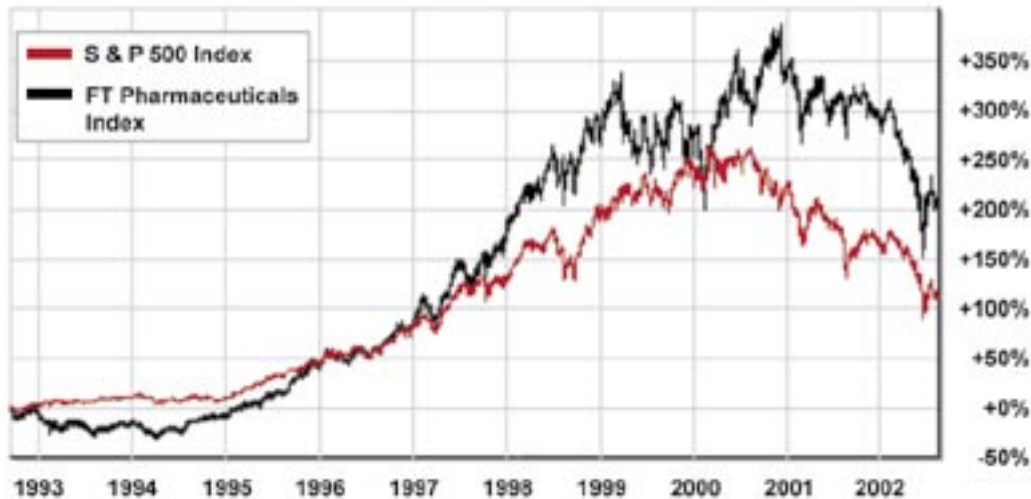
In 2010, Pharma will engage much more fully with healthcare payers, physicians and patients as well. In this way, it will get better feedback – both clinical and commercial – at a much earlier point in the development process. It will also be able to promote accurate diagnosis and treatments, and support medical practitioners.

Sales and Marketing

Many of the new medicines that are made will cover secondary rather than primary care, so they will be marketed differently – using tightly focused sales teams, trained to converse with specialists. But all new medicines will be promoted on the basis of the specific disease states they address, rather than whether or not they work better than competing products. They will be supported by objective evidence and priced according to the medical results they deliver, not the price of rival drugs that are already on the market. And a substantial part of their value will lie in the services that come with them.

These services will form the backbone of a comprehensive support network that helps individual patients to identify when they *really* need to see a doctor; to manage the particular disease states from which they suffer; and to understand why they should keep taking the medicines they have been prescribed. In conjunction with targeted treatments and remote monitoring, better persistence will improve the healthcare patients receive. It will also boost the industry's revenues.

Between Mid-1993 and Mid-2000, The FT Pharmaceuticals Index Rose by More Than 350%, But It Has Since Lost Nearly Half Its Value



Source: BigCharts.com

The Threshold of Innovation

Our research shows that these changes will be driven by the shifting balance of power between Pharma and its customers. Governments, healthcare insurers and patients are increasingly dictating the sort of new drugs they want and the prices they are willing to pay. In short, it is the healthcare payers – not the drug makers – that are now defining the threshold of innovation. They are also squeezing every ounce of value out of products that are already available, so they are raising the threshold of innovation ever higher.

The situation has been compounded by lack of productivity in the laboratory, the impending expiry of the patents on numerous blockbusters and various other problems. Together, these difficulties have seriously dented Pharma's recent financial performance. Between mid-1993 and mid-2000, the FT Pharmaceuticals Index rose by over 350%, despite the long shadow cast by former President Bill Clinton's plans to reform the US

Pipelines Under Pressure

- *Falling productivity in research and development.* In 2001, the US Food and Drug Administration approved just 24 new molecular entities (NMEs) – fewer than in any of the previous six years – even though the industry's R&D spend has doubled since 1997. This trend looks set to continue; the FDA had approved only 10 NMEs by September 2002.
- *Product failures in late-stage development and the marketplace.* In the three years to 2001, at least 28 products with potential peak sales of more than \$20bn were terminated in late-stage development. Between 1997 and 2001, 12 drugs with peak sales potential of more than \$11bn were also withdrawn from the market on safety grounds.
- *Multiple patent expiries.* Within the next five years alone, the US patents on 35 drugs with global sales of more than \$73bn will expire.
- *Intense therapeutic competition.* There are four Cox-2 inhibitors on the market and nine similar drugs in the industry's late-stage pipeline or awaiting approval – just one example of the way in which therapeutic competition is increasing.
- *Shortage of blockbusters in the pipeline.* Industry experts predict that there are only 14 potential billion-dollar blockbusters in the pipeline between 2003 and the end of 2008, and none of these new drugs is expected to make as much money as the current top sellers.

healthcare system. In the two years after that, the Index lost nearly half its value. The dot-com crash and the general economic downturn have contributed to the huge slump in share prices, but at least 13 drug makers have issued profit warnings since October 2001 – and there has also been a sea change in investors’ attitudes toward the sector.

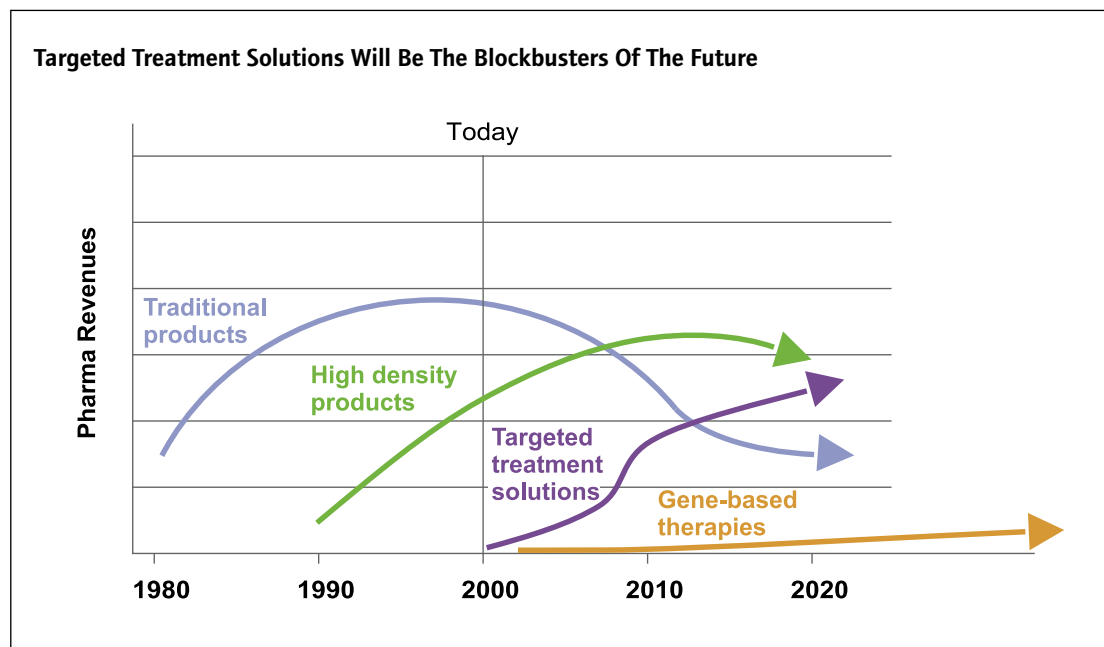
We predict that, if the industry continues on its current course, the many problems it now faces will prevent it from delivering growth of more than 5.3% CAGR between now and the year 2010. This is significantly lower than the 9% some analysts forecast and massively below the double-digit growth Pharma enjoyed in the last decade.

The Move to Targeted Treatment Solutions

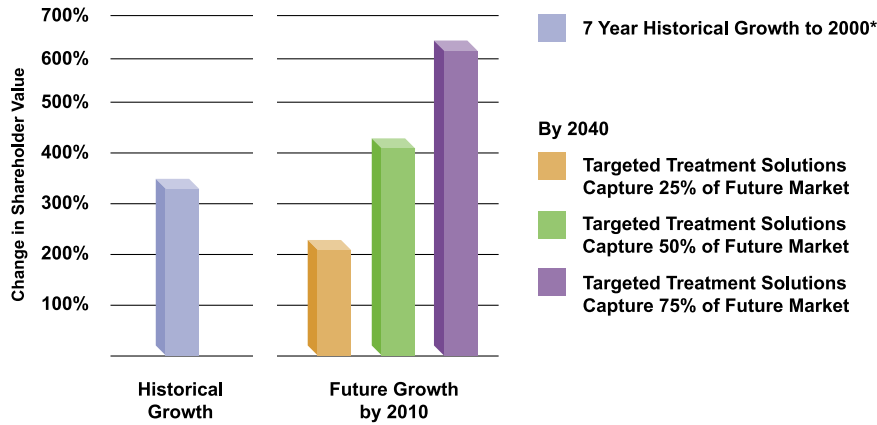
Fortunately, there *is* a way forward. Genomics, proteomics and metabonomics will give Pharma the tools with which to understand and define diseases

much more accurately – and this is where their real promise lies. The molecular sciences have produced plenty of new biological targets, but scientists currently know very little about which targets are relevant or which diseases they are associated with. So these new sciences will exacerbate attrition rates and fragment the market for companies that persist in using the traditional approach to discover and develop new drugs.

But the most pioneering pharmaceutical companies will adopt a totally different approach. They will focus on defining diseases at a molecular level, distinguishing between different disease states, and connecting the many potential new targets genomics has identified with particular disease pathologies and the molecular mechanisms in which they are involved. They will then be able to develop packages of treatments and support services for patients with specific disease states. These targeted treatment solutions will be the main blockbusters of the future.



Companies That Make Targeted Treatment Solutions Could Enjoy Even Greater Growth Than They Did In The Last Decade



*Source: BigCharts.com

A Totally New Business Model

Companies that want to make targeted treatment solutions will need to start by acquiring a comprehensive understanding of how specific diseases work, rather than drawing on academia for such information. They will also need to transform the way in which they discover, develop, market and manufacture new drugs.

In total, however, the new model we envisage could reduce the time from target identification to launch from 10-12 years to between three and five years. It could also increase success rates from first human dose to market by a factor of four; and slash costs per drug from an average \$800m to as little as \$200m.

The Financial Promise of Targeted Treatment Solutions

Most companies will be unable to make an immediate transition from the old to the new way of doing things. So while they are building the infrastructure and acquiring the skills to create targeted treatment solutions, they will simultaneously have to maximize the value of their existing portfolios. But though this is a huge challenge, our work suggests that the rewards will more than justify the effort. We have modeled the impact of various scenarios on the industry's shareholder value. Our analysis shows that, regardless of what happens over the next eight years, Pharma *cannot* stand still.

Companies that fail to respond to the market conditions which are now emerging – and those that are currently most successful may well be those that most resist making the necessary changes – will see their value continue to plummet. But even those that are most effective in maximizing revenues from traditional products will not be able to generate sufficient growth.

It is only by entering totally new terrain that Pharma companies can hope to produce the truly innovative medicines for which people will readily pay. We estimate that, even if the market for targeted treatment solutions is slow to get started, companies that learn how to make such medicines could triple their shareholder value by 2010. If the market for such medicines takes off more rapidly, they could enjoy almost double the growth the industry enjoyed in its heyday – a prize well worth the effort required.

How to Win the Game

What should pharmaceutical companies do to pave the way for targeted treatment solutions?

1. Create a disease-centric approach to discovery and ensure that they own the intellectual assets pertaining to the diseases on which they choose to focus, rather than relying on academia to generate that knowledge
2. Transform their development processes with the introduction of adaptive and in-life trials
3. Capitalize on the power of technology
4. Construct an outcomes-based sales and marketing model
5. Build a flexible, integrated supply chain that covers multiple kinds of products
6. Forge closer relationships with the industry regulators, healthcare insurers and physicians; and
7. Promote the use in-home diagnostic, monitoring and communications technologies that can deliver real-time access to patient data.

How to Stay in the Game Long Enough to Win It

What should pharmaceutical companies do to survive in the short term?

1. Review their entire R&D portfolio to assess the threshold of innovation each new product must overcome by the projected launch date
2. Maximize the value of their overall portfolio by:
 - Optimizing prices
 - Improving compliance and persistence
 - Maximizing their market reach
 - Streamlining their supply chain and support processes
 - Acquiring new products
 - Extending the life of those products; and
 - Making their R&D as efficient as possible.

Companies that learn how to make targeted treatment solutions will be able to surmount the rising threshold of innovation – and it is not just investors who will benefit. So will healthcare insurers, physicians and patients, for Pharma will then be able to develop commercially viable products and services for patients with particular genotypes and disease pathologies.

Authors

Steve Arlington, PhD

Sam Barnett, EdD

Simon Hughes

Joe Palo

External Sources of Assistance

CMR International

Datamonitor

PricewaterhouseCoopers

John Urquhart, Professor of Pharmacoepidemiology,

Maastricht University and Professor of

Biopharmaceutical Sciences, UCSF, San Francisco

Editorial Adviser

Helen Kay, PhD

We should also like to express our gratitude to the many senior pharmaceutical executives who have given us valuable input.

About IBM Business Consulting Services

With more than 60,000 consultants and professional staff in more than 160 countries globally, IBM Business Consulting Services is the world's largest consulting services organization. IBM Business Consulting Services provides clients with business process and industry expertise, a deep understanding of technology solutions that address specific industry issues, and the ability to design, build and run those solutions in a way that delivers bottom-line business value.

To learn more about our global Pharmaceuticals and Life Sciences practice,
please visit <http://www.ibm.com/services/strategy/industries/lifesciences.html>
or contact an IBM Business Consulting Services representative.

please contact

Steve Arlington – London
steve.arlington@uk.ibm.com
+44 20 7968 5196

Simon Hughes – London
simon.hughes@uk.ibm.com
+44 20 7968 5186

Sam Barnett – Philadelphia
sam.barnett@us.ibm.com
+1 215 972 5071

Joe Palo – Florham Park
joseph.d.palo@us.ibm.com
+1 973 236 5480

Eimei Shu – Tokyo
eimei.shu@jp.ibm.com
+81 3 6250 8500



© Copyright IBM Corporation 2002

IBM Global Services
Route 100
Somers, NY 10589
U.S.A.

Produced in the United States of America
11-02
All Rights Reserved

IBM logo is a registered trademark
of International Business Machines
Corporation in the United States, other
countries, or both.

Other company, product and service
names may be trademarks or service
marks of others.

References in this publication to IBM
products and services do not imply
that IBM intends to make them available
in all countries in which IBM operates.