



DealReader Pharmaceutical Markets

Re-Phar-Mation

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**“Doubt is not a pleasant condition, but
certainty is an absurd one.”**

- **Voltaire**

Lincoln Healthcare: Pharma, Pharma Services and Pharmacy M&A Clients and Counterparts



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The Present

Large pharmaceutical companies, along with commercial biotech and generic drug companies, form the core of the healthcare industry which underlies the med-tech, CRO, CMO, diagnostic and services verticals. Between 2006 and 2015, nearly 300 new drugs were brought to market, driving 10% annual growth. However, there are tectonic shifts occurring in that world which are eroding the industry's traditional economic models and, therefore, drastically changing the healthcare landscape for years to come.

For the past decade, mergers in the pharma and biotech industries have masked the following underlying problems: shrinking new drug pipelines, patent expiries and changing

demographics. In the first decade of the 21st century, there were as many as 1,345 mergers announced in the pharma and biotech sector. This activity has been augmented by financial tools such as inversions. However, financial engineering is not a reliable tool going forward, as the \$160 billion Pfizer/Allergan saga showed us recently. Now, Allergan must rely on its deep pipeline and cash reserves to attract other strategic partners and will be touting its pipeline of products until another buyer emerges. While larger mergers will not disappear, executive management teams will increasingly need to go back to the fundamentals.

The New Environment

The following emerging issues will complicate healthcare CEOs' decision making in the coming years. **Stricter regulations** in the U.S. and abroad will add hurdles to the commercialization of drugs. There is a **revolt on prices** in both emerging and mature markets which has put pressure on profits. Increased scrutiny and **focus on outcomes** are becoming more important than merely targeting disease states; *The New England Journal of Medicine* concluded that the past ten years had not demonstrated any improvement in health outcomes. **Return on R&D** expenditures over the past 20 years has fallen, from an industry average of 20% down to 10% according to *KPMG*. Over 70% of big pharma's total drug sale revenues are derived from patented products, but that is exactly where they are very vulnerable, as an increasing number of drugs are coming off patent. **Approvals of new molecular entities and biologics** have remained fairly flat over the past ten years.

How are the pharma companies going to deal with these realities? The stakes are high in a market estimated by PriceWaterhouseCoopers (in their Pharma2020 report) to be \$1.6 trillion by 2020.

Data of all sorts – scientific, behavioral combinatorial – create both opportunity and danger for the pharma industry. In 2001, it cost \$95 million to read an entire human genome, according to the *National Human Genome Research Institute*. "Today, two leading companies can do so for as little as \$1,000 – in a matter of hours," according to a study conducted by *Pricewaterhouse*. The development of readily available and **inexpensive gene sequencing** has enabled

data to be accessible to doctors and patients, making it increasingly part of everyday medicine.

In addition to data, increasingly strict regulations, more scrutiny on mergers, rising healthcare costs, the rise of generic pharmaceutical companies and the desire for more affordable healthcare will add to the complexity of determining what future pharma companies will look like.

Patient centricity is an umbrella term which covers a number of changes that will take place in the years ahead. Health outcomes, rather than just products and services targeting high-cost elderly patients and their chronic diseases and co-morbidities, are forcing governments, regulators, payers and healthcare providers to shift their focus towards patient care management. Patient centricity is a broad and complicated change. It is not only about improving medical outcomes per se. It is about compliance, affordability, ease of use, monitoring away from traditional facilities-based care and integrated, coordinated, multi-disciplinary care management. The goal here is to keep patients stable, treated and monitored in the least costly healthcare setting. At the same time, patients are getting greater knowledge and access to information: the e-patient is born.

In this complex environment, strategies of big pharma seem to range from **innovation-based to market-driven**. Roche tries to position itself on the innovation end of the spectrum and attempts to sell "innovative, higher priced products to the growth market." GSK is an example of a company on the

market-driven end of the spectrum. In between those two, Eli Lilly focuses on selling branded medicines and Sanofi invests heavily in building its generics area. At the core – the drug pipeline – it is important to keep in mind that 90% of trials that back clinical testing will fail and more blockbuster drugs will become outdated. Strategies of pharma companies must include reducing the failure rate of new drug development, making it as economically efficient as possible.

The collaborative age of pharma is born. To augment the above strategies, some pharma companies are for the first time engaging in

collaborative partnerships with competitors, government entities and academic research centers. GlaxoSmithKline recently formed a pre-competitive collaboration with Wellcome Trust Sawyer and the *European Bioinformatics Institute*. Similarly, Pfizer and a host of other competitors have worked together with Assay Depot to share pre-clinical research. Many others have entered into collaborations in order to leverage science and marketing expertise. Examples include Astra Zeneca and Columbia University Medical Center, as well as UCSF and Pfizer.

The Fundamentals

The pharma industry, a pillar of stable dividends and growth for the past half century, is now caught in a web of uncertainty and change, but also remains a vector to help to potentially revolutionize the healthcare industry. In the midst of this change, the core fundamentals will remain important:

- Increased effectiveness and efficiencies in new and differentiated drug development
- Ongoing refinements in clinical trial management and greater speed to market
- Enhanced value propositions to payers and providers through drug differentiation and wrap-around service for improved health outcomes
- To the extent acquisitions are needed, focus on more strategic acquisitions to

enhance the core capabilities and strategies of the acquiring company

- Enhanced proof-points around lower overall healthcare costs in particular drug categories
- Outsourcing functions that are necessary for pharma companies, but where in-house capabilities do not generate sufficient ROI
- Partnerships and collaborations that drive to-market improvements and leverage capabilities to reduce overall costs

As one can see, change in the development and distribution of drugs is inevitable. However, despite the uncertainty of the shifts described above, healthcare will play an increasingly large role in the economies of both the developed and developing world.

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