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PHARMA BUSINESS DISRUPTIONS CREATE BIOTECH OPPORTUNITIES

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Blockbuster drugs (those that generate over $1 billion in annual sales), the cash cows of the pharmaceutical industry, are being cornered by the patent cliff and replaced by low-priced generic drugs. Most blockbusters are already intrinsically ageing since they are the product of decades-old science.

Understanding the Patent Cliff

Pharmaceutical patents provide companies exclusive rights to market their drugs for up to 20 years. During this time, they can recover the substantial investments required for drug development, including research costs, clinical trials, and regulatory approval. However, once a patent expires, the door opens for generic manufacturers to enter the market with much cheaper versions of the same drug. This competition can lead to a dramatic drop in sales for the original drug – a phenomenon known as the patent cliff.

The financial impact of this is often profound. For instance, when Pfizer's patent on Lipitor expired in 2011, the drug's revenue plummeted by over 60% in just two years, dropping from $10.7 billion in 2010 to $3.9 billion in 2012. This dramatic decline highlights pharmaceutical companies' vulnerability as their most lucrative patents reach the end of their lifecycle.

Meanwhile, science and medicine are redefining disease entities, breaking down diagnostic groupings based on the driving molecular mechanisms.

For example, cancer types, defined by 20th-century light microscopy, are now being categorised by their molecular signatures. These subgroups have distinctive biological characteristics and respond to distinct treatments. Keytruda, the widest-used immune-oncology

drug, is specifically indicated for advanced solid tumours with a specific molecular signature. It is increasingly possible to directly identify and target those patients who can directly benefit from treatment. Currently, it may be necessary to treat ten patients to have one responder. The other nine patients do not benefit but may have side effects and cost money to treat. This is known as the “Number Needed to Treat” (NNT). The goal is to reduce the NNT to as close to 1 as possible so that only patients who have the potential to respond are treated. The result is indication shrinkage. Indication shrinkage opens the door to more efficient drug development and better use of healthcare resources.

This is the underlying basis for precision medicine. Once the responders can be identified, the number of patients needed to be studied in a clinical trial goes way down. Gene therapy is an extreme example. Enzyme replacement therapy for rare genetic diseases like Gaucher disease is an established and successful business model. Only patients with a diagnosis are treated, and almost all of them respond. This is the rare disease model. And the more we understand, the more we realise that many common diseases are made up of a mosaic of subtypes.

Precision medicine is efficient and has two components: the disease and the patient. Indication shrinkage changes business models, drug development, and medical care strategies. To the extent that drug development costs are fixed, smaller target populations mean higher prices per person to achieve the same return on investment.

By embracing precision medicine and building strategic partnerships, pharmaceutical companies can navigate this difficult period and emerge stronger, with a renewed focus on creating the next generation of life-saving therapies.

As the healthcare landscape continues to evolve, the companies that can adapt and leverage the opportunities presented by the patent cliff will be well-positioned to lead the industry into the future.

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