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Opinion

Risk Management of the Pharmaceutical Companies

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Opinion

Compared with other industries, the pharmaceutical industry is driven by R&D and high regulations, as well as increasing product complexity and quality requirements [1]. Indeed, it usually takes more than 10 years for a new flagship drug to be successfully developed, approved, and launched into the market. Moreover, it costs at least US $1 billion to develop a new drug [2]. The long development and testing cycle, as well as the uncertain success prospects, require pharmaceutical companies to resist and manage risks. Over the years, the pharmaceutical industry has therefore been adjusting its business model to develop drugs that can be used by the widest segment of the population as possible, through a financialized approach. Indeed, ensuring the long-term profitability and revenue of a company, upon the launching of new drugs, raises serious concerns for the involved parties in the pharmaceutical industry [3]. The risks faced by pharmaceutical enterprises include patent cliff, declining market demand, and the impacts of external financial pressures.

Patent Cliff

Purdue is an example that shows how a company deals with the risks of patent cliffs, which are one of the major issues facing the pharmaceutical industry [4]. Patent cliffs refer to the loss of exclusivity and intellectual property rights regarding one or more products. As such, patent cliffs can have a significant negative impact on the company's financial performance. This dynamic is forcing "Big Pharma" to look for new revenue streams. For example, in the 1990s, the patent for "MS Contin-Purdue's best-selling drug at the time-was about to expire" [5]. To maintain its market-share, profitability, and respond to the risk of patent cliff and competition posed by generic manufacturers, Purdue needed to quickly develop and patent a new flagship product. As a result, "OxyContin was developed in the early 1990s, approved by the FDA in 1995, and released to the market in 1996" [5]. "It was marketed as a "wonder drug" an innovative painkiller that would revolutionize chronic pain management" [5]. The marketing strategy adopted by Purdue was very aggressive and-rather than being based upon extensive scientific research and innovation-it was founded on unsustainable claims. Purdue, to expand its presence into the non-cancer pain market, "claimed that OxyContin offered 12 hours of pain relief, compared to 4 to 6 hours offered by its competitors" [6]. They also "placed special emphasis on the claim that the risk of addiction of OxyContin was low, asserting it at less than 1%" [6]. The "aggressive marketing campaign proved to be a commercial and financial success". Indeed, "OxyContin sales represented $48 million in 1996, $1.1 billion in 2001 and $3 billion in 2010" [7]. Here, a financialized company dealt with the risk of a patent cliff that threatened its profitability by quickly developing and marketing another drug that it could patent, resulted in very negative public health outcomes.

Declining Market Demand

Gilead and Purdue have similar ways of managing the risks of a financialized business environment. Although their target markets are totally different, both companies sought to generate demand for new medicines, to "expand" the conditions for which their respective products needed to be used. Gilead is undoubtedly the leading company in the HCV and HIV drug markets. However, it faced the risk of a declining demand in the HCV market, as its drugs are "too effective to maintain profits". Indeed, offering a drug that can cure a disease can help patients suffering from said disease in the short and long term, while it is only profitable for the medicine's

manufacturer in the short term. Gilead is therefore facing a decline in demand and price for HCV products, as competition is fierce, and these drugs almost cure the disease. Similarly, if Gilead was to come up with a drug combination that could cure HIV, the drug will devour and possibly eliminate existing profits from other HIV drugs [8].

Therefore, Gilead's strategy is to explore and innovate in the HIV drug markets, to face the risks of declining demand by treating the risk and pre-empt the disease, rather than treating the disease itself. As such, Pre-Exposure Prophylaxis (PrEP) is, for example, a treatment designed to prevent one from contracting HIV from unsafe sexual intercourse or drug injection. There are two medications approved for use as PrEP: Truvada and Descovy, which are all produced by Gilead [9]. Truvada-when taken daily or as directed by physicians-is more than 99% effective in protecting against HIV infection [10]. Nevertheless, Gilead did not choose a marketing campaign to promote its PrEP drugs as large as the one it chose for its HCV drug, Harvoni (around $100 million dollars) [8]. The company only spent hundreds of thousands of dollars a year to promote the PrEP drug Truvada.

Arguably, much earlier on, Gilead should have made use of the influence of existing drugs to further depict PrEP drugs as the goal of HIV prevention-under a public health framework. The marketing of the drug is mainly aimed at the queer community with the purpose to educate people about the natural evolution of risk factors and preventive measures-and how the individual can protect themselves from infection [11]. In this case, health is regarded as a product of the free market, and its purchase depends on individual discretion [10]. To hide this complacency regarding the uneven distribution of health, Gilead puts the burden of health on patients themselves [10]. The strategy it uses to reproduce the reality of pathology even can be glorified as social responsibility [10].

External Financial Pressure

Under the trend of globalization, the financialization environment is changing all the time. If pharmaceutical companies fail to keep up with the pace when developing new business models or make a wrong assessment of the changing financial environment, they can only maintain revenue through speculation. But it could put the companies in a worse position. Without proper policy intervention, the increase and change of investment will not only weaken the effective market response ability, but also lead to the decline of drug R&D ability [12]. Amgen has introduced another way to manage the external risk (this will be discussed in detail further in the R&D and innovation section). The firm is facing the situation where their four top-selling products have sales that are either flat or declining and their leading drugs are no longer being the growth drivers the company needs. Amgen's risk management strategy is to make full use of its current market position, without making additional investment in product innovation by the means of mergers and acquisitions. According to Amgen's representative, acquisitions are of high importance for Amgen at the current stage [13].

In the case of Teva, all its profits come directly from their pharmaceutical sales and the company is known for manufacturing generic medications [14]. There is very little diversification within their pharmaceutical sales, which means they are facing great stress and risk to compete in this arena. In 2016, because of succumbing to the financial pressure, Teva paid $40.5 billion dollars for the generic-drugs division of Allergan [15], which turned out to be a great failure at last. In the face of this criticism by shareholders, "Teva pharmaceuticals began a mass "selloff in its debt and equity" to somehow recoup the costs of doing business [15]". Nevertheless, "other fiscal consequences arise and, once more, they are at the behest of the shareholders and their respective concerns".

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