DON'T POKE THE BEAR: THE EFFECT OF PHARMACEUTICAL PRICING ON PERCEPTION AND FUTURE INNOVATION

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Companies like Turing Pharmaceuticals and KV Pharmaceuticals have grabbed headlines recently for their aggressive pricing strategies. Whether these strategies are justified or even successful is not the point. Rather, what is important is the negative public perception that significant price hikes create for the industry as a whole. In this climate, the industry needs to do a better job of talking about how prices are set and how that money is invested—otherwise we risk losing control of how we price our products and operate our businesses.

Risk of Regulation

Negative headlines raise alarms not just for insurance companies. The rise of high-deductible health plans means that the average patient has more skin in the game than in the past. The cost of healthcare is on everyone's mind, and when there is public outcry, regulators begin to take notice, especially in an election season.

In the wake of Turing's 5,000 percent increase in the price of Daraprim, presidential candidate Hillary Clinton unveiled her plan to reduce the cost of prescription drugs. In addition to promoting generic and imported drugs, allowing Medicare to negotiate lower drug costs, and capping out-of-pocket expenses for individuals with chronic health problems, Clinton's plan would push pharmaceutical companies to reinvest their profits into research and development.[1] Government should not have a seat at the table in making these fundamental strategic decisions.

Of course, we know that the industry already reinvests a significant amount of money back into R&D. Further, it is important for drug manufacturers to demonstrate a potentially high return on investment in order to attract the investors they need to finance high-risk, high-innovation research and clinical trials.[2]

What we see now is that investment in innovation has paid off. The number of new drugs approved by FDA is high, from an average of 31 in the 1990s, to 24 in 2000s, to 32 over the last 5 years.[3] In addition, in the 1990s and 2000s, many of the approved therapies were later entrants to already-crowded markets, such as statins for cholesterol, proton-pump inhibitors for gastroesophageal reflux disease, and various therapies for hypertension. These products competed based on modest improvements in profile, nothing like the dramatic improvements being offered by the new generation of products being approved today.

We have entered a golden age of pharmaceutical innovation, with the emergence of first-in-disease therapies for devastating conditions, such as Vertex Pharmaceuticals' Kalydeco, the first-ever disease-modifying therapy for cystic fibrosis. We are seeing new options that are proving to be more efficacious and more convenient for chronic progressive diseases like multiple sclerosis, rheumatoid arthritis, psoriasis, Crohn's disease, and others. New options for serious and challenging cancers like melanoma are giving hope to oncologists and their patients. And new drugs and regimens are helping to make manageable historically daunting conditions such as myelodysplastic syndrome or breast cancer. This golden age of innovation is the result of sustained investment in new drugs.

High Cost of Drug Development

Developing drugs is a high-risk endeavor. According to a 2014 study by the Tufts Center for the Study of Drug Development, developing a new prescription medicine that gains marketing approval is a process that can last longer than a decade at an estimated cost of $2.56 billion. This figure represents a 145 percent increase in the cost of developing a new drug compared with the figure Tufts cited in a study published in 2003—an increase driven in part by the industry addressing increasingly challenging targets.[4] If Developing drugs is a high-risk endeavor. According to a 2014 study by the Tufts Center for the Study of Drug Development, developing a new prescription medicine that gains marketing approval is a process that can last longer than a decade at an estimated cost of $2.56 billion. This figure represents a 145 percent increase in the cost of developing a new drug compared with the figure Tufts cited in a study published in 2003—an increase driven in part by the industry addressing increasingly challenging targets.[4] If successful in the increasingly expensive task of developing a new drug, companies only have a relatively small patent window to recoup that investment.

Venture capitalists are willing to put up the seed money to develop new technologies, the public markets are willing to fund unprofitable biotech companies, and

pharmaceutical companies are willing to invest in continued R&D all because of the promise of a protected reward. Anyone who believes it possible to reduce the reward at the end of that long and challenging path without also reducing the amount of innovation is dangerously deluded.

Turning the Tide of Public Perception

Despite the unprecedented success of pharmaceutical development in recent years, negative headlines dominate the news. To begin turning the tide of public perception, company leaders need to keep perception in mind when making pricing decisions. They must maintain a broad view as to how their pricing decisions will affect the industry as a whole. While aggressive pricing may bring an organization short-term gain, if these actions lead to significant changes to the regulatory landscape and approval process, companies may experience less profit and thus less innovation in the long term.

Perhaps pharmaceutical pricing is unfairly scrutinized. After all, no one questions why Apple should charge $600 for a phone that costs $15 to manufacture. But when it comes to treating and curing disease, a moral component enters the equation for which a simple cost-of-goods explanation is no longer adequate. This is a reality we accept as an industry. Therefore, we have a right to be concerned when the aggressive pricing tactics displayed by Turing CEO Martin Shkreli have a psychological impact on the public and tarnish the entire industry. Our current drug approval process generally works well, but while Shkreli and others are working within the rules, they risk breaking the system by poking the regulatory bear.

Our Responsibility

As an industry, it is important for us to do a better job of telling the story of our successes. We need to make clear the reasons why drugs cost what they do and show how profits earned are the fuel that drives the next generation of innovative products. If we do not tell this story well, we run the risk of backlash, ranging from physicians having less willingness to prescribe our products all the way to government negotiating on price or instituting outright price controls. This would be an outcome none of us can afford—in the industry, or as a society.

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About the Author

Jonathan Hodgson is a Managing Director with EVERSANA MANAGEMENT CONSULTING and has more than 15 years of experience helping biopharmaceutical companies make better strategic decisions in the areas of commercialization, R&D, portfolio planning, launch pricing and reimbursement, forecasting, asset valuation, and more across a broad range of therapeutic areas.

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