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EDITOR'S PAGE

Cardiovascular Drug Pricing

Less Innovation for More Access?

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The national debate continues to heat up in the United States around drug pricing and the need for lower drug prices for the citizens that we serve. In reviewing this complex economic situation, it has become clear that the prices of drugs in the United States are often twice as high as those in countries of similar socioeconomic status. Why is this so? The United States has a unique policy toward drug pricing in which there is no regulation for the negotiation of pricing when new prescription drugs come onto the market. This is in stark contrast to other countries, where government agencies meet with pharmaceutical companies and discuss and agree on an appropriate price. Furthermore, approval agencies typically make decisions about whether new drugs represent a true advantage over existing drugs on the market, and therefore the discussion of priority occurs at a very early stage.

For example, when one looks at the process in Australia, over 50% of new cancer drugs that would be potentially approved in the United States are not approved in Australia, because of the belief that the incremental advantage is not enough over existing therapies. In addition, if a drug is approved to come onto the market, there is a separate discussion about pricing between the government and the pharmaceutical industry. This discussion often results in a negotiated position that is far below the unregulated position of the United States, and, therefore, the United States is left with the burden of carrying the highest cost for new drugs in the world, which economically restricts access.

At a minimum, over 25% of patients have significant difficulty in paying for their medication. Cost effectiveness is not entered into the equation in the approval process in the United States, in contrast to the United Kingdom and other countries. If it appears so clear that there is such asymmetry in drug pricing in the United States, should the policies being discussed at the national level be straightforward and accepted by everyone? Well, not so fast. It turns out that there is a delicate balance between drug pricing and innovation. A total of 42% of the margins for pharmaceutical companies occurs in the United States. Therefore, a reduction in that margin by reducing drug pricing will have a significant impact on research, development, and the opportunity to bring new therapies to the market both globally and to U.S. citizens (1). In such a case, it is believed by many that investment in new drug therapies for diseases such as heart failure and the comorbidities associated with heart failure would slow down. Some economists have estimated that the number of new molecules reaching the market would be reduced to such a level that one could estimate a reduction in life expectancy in future generations.

If this is the case, then what are the solutions? Can we balance somewhat less innovation for more access? We certainly have to do something in the United States, as the United States cannot bear all the cost of innovation, therapeutic development, and access to new molecules. Perhaps a better approach would be harmonization of drug pricing across the globe. Why should, for example, citizens of Switzerland pay one-half of the price that the citizens of the United Kingdom pay for novel therapeutics, who in turn pay one-half of the price of citizens in the United States, all with the same socioeconomic status and income-earning potential of their citizens. It is clear when there is a gradient of socioeconomic status that we should have price differentials, particularly in third world countries where the need for novel therapies may have an even greater impact. Yet, the United States should not have to bear the cost of innovation through higher drug prices for the rest of the world. There should be a global middle ground that will allow us to keep the engines of innovation moving forward at an exceptionally fast pace while allowing

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greater access to lifesaving and important therapies. Therapies that have little advantage and efficacy over existing therapies should be considered with greater scrutiny.

In addition, we cannot continue to embark on therapeutic development programs that take 10 to 12 years and over one-half a billion dollars, leaving companies with a limited patent life and return on investment. There are 2 opportunities that could help with this: 1) improving the therapeutic development process by greater efficiency, greater value of conduct, and reducing the burden of data collection and monitoring, so that the therapeutic development cost can be less (2); and 2) extending the patent life of lifesaving therapies in exchange for the reduced cost, so that the total value of return would be some reasonable percent of the investment and allow innovation to continue. So, when it comes to drug pricing, let us try to look for more access without compromising too much innovation. Our patients deserve it.

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