ADVANCES IN DRUG DEVELOPMENT

Current Developments in Oncology Drug Research

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Variability in Global Drug Prices

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H&O Why are drug prices in the United States so high?

ASK Brand-name drug prices are on average approximately 2 to 4 times higher in the United States than in other comparable industrialized countries. Some of the starkest differences in drug prices between the United States and other countries occur in the oncology field. In the United States, pharmaceutical companies have been permitted to charge whatever they want for their brand-name drugs at the time of launch. In other industrialized countries, after the drug is approved by the regulator, the next step is to compare a drug's clinical benefit with other available alternatives. Then price negotiation happens, often at the country level, based on the clinical benefits that the drug provides. A new drug with similar efficacy to existing drugs is generally not allowed to cost more. This process makes an important difference in reducing costs for drugs, especially those that do not offer many benefits over other available alternatives. In the United States, we have traditionally lacked this second crucial step.

Another important factor is that in other countries, pharmaceutical companies are not allowed to increase prices year after year for a drug when the basic use remains the same. In the United States, brand-name drug manufacturers have long been able to raise prices for approved drugs whenever they want to based on whatever criteria they choose, although the recent Inflation Reduction Act for the first time imposed restrictions for price increases in Medicare.

The Inflation Reduction Act also instituted limited government negotiation for Medicare drug prices, for the first time in US history. Medicare was given the ability to negotiate the prices of selected top-selling drugs that have been on the market for at least 9 years (13 years for biologics) with no generic alternatives.

H&O What other types of policies could be implemented in the United States to reduce drug prices?

ASK Another key way to reduce drug prices is to take steps to improve direct competition with generics or biosimilars. In the United States, the only real intervention that consistently and substantially lowers drug prices is when generic drugs enter the marketplace at the end of a brand-name drug's period of exclusivity. The competition from generic drugs usually leads to substantial reductions in spending. Unfortunately, brand-name drug companies can obtain numerous patents on their drugs—some of which may be overly broad or have been granted improperly—and use strategies to delay and undermine entry of generics and biosimilars. Spending on drugs therefore remains higher for longer than it needs to be.

Policymakers and regulators need to take steps to prevent these types of actions to improve market competitiveness and lower spending.

H&O Are there any other barriers to reducing drug prices in the United States?

ASK A major barrier to altering drug policy in the United States is the political power of the pharmaceutical lobby, which makes political change very challenging. This factor was one reason it took so long to implement Medicare drug-price negotiation reform, even though vast majorities of consumers agreed with the policy. Another barrier to better prices are rules in the United States that make it challenging for individual Part D plans and other payers to try to negotiate prices, such as state laws that require insurance coverage of certain drugs.

If we want to continue to facilitate important innovations that will lead to the great treatments of tomorrow, it will be necessary to maintain—or better yet increase—funding for the National Institutes of Health and make further investments in basic and translational science.

A pushback to these reforms is the concern about the effect on innovation. However, it is important to understand that transformative drug innovation tends to originate with publicly funded research at academic and government laboratories. If we want to continue to facilitate important innovations that will lead to the great treatments of tomorrow, it will be necessary to maintain—or better yet increase—funding for the National Institutes of Health and make further investments in basic and translational science. Since drug companies also play an important role in the process of new drug development, we similarly need to make sure that we are paying fair prices for drugs once they are approved. The reforms I have mentioned may still compel the country to pay a lot of money for important innovations. We will be better equipped to pay for these innovations if we stop spending so much money for marginal or limited innovations, which is what we do now, or stop paying high prices for excessive periods of time before generic competition. The concerns about the effect of these reforms on innovation tend to be a scare tactic that is used by the drug industry to prevent policies that would promote fair and reasonable drug prices.

Disclosure

Dr Kesselheim reports consulting in a lawsuit on behalf of a class of private insurers against numerous generic drug manufacturers relating to price fixing and in a case on behalf of a class of plaintiffs against Gilead related to its tenofovir-containing products.

Suggested Readings

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