Can the high cost of prescription drugs in the US be contained?

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In a Special Communication in *JAMA*, "The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform," Kesselheim and colleagues reviewed the peer reviewed medical and health policy literature from January 2005 to July 2016 to understand the sources of high prescription drug prices in the U.S., and to survey the range of solutions offered to help contain drug spending. Researchers found that per capita prescription drug spending in the U.S. is the highest in the world, and is largely driven by brand-name drug prices that are set, at introduction, based on 'what the market will bear' and often rise substantially during competition-free periods of market exclusivity maintained by a combination of regulatory exclusivity and patents.

Between 2013 and 2015, net spending on prescription drugs increased approximately 20 percent in the U.S. Prescription medications now comprise an estimated 17 percent of total health care costs and prescription medication coverage constitutes 19 percent of employer-based insurance benefits.

"Unlike other countries, the U.S. health care system allows manufacturers to set their own price for a given product," stated Kesselheim. "High drug prices are the result of the increasing cost and complexity of drug development but also are the result of government protected monopolies to drug manufacturers, requirements imposed on government-funded drug benefits, and restrictions on public and private health insurance providers to negotiate lower drug prices."

In the article, researchers explain that drug manufacturers automatically earn one type of market exclusivity upon FDA regulatory approval of a new product— a guaranteed period of about seven years before a generic competitor can be sold. Biologic drugs—complex, often-protein based therapeutics—get 12 years of guaranteed protection. The total length of market exclusivity is determined by a manufacturer's patents which can last 20 year or more.

High drug prices have important clinical consequences," Kesselheim said. "Increases in co-payments can reduce the affordability of prescriptions. Often patients do not fill their prescriptions on a consistent basis, and high prices can be an important contributor to non-adherence."

The authors indicate that high prices have traditionally been limited to brand-name drugs that treat rare conditions. However, drugs that treat conditions affecting millions of individuals in the U.S. also now have high costs. Researchers cite the example of new oncology drugs entering the market at a price exceeding $100,000 per course of therapy and the 300 percent increase of the average price of insulin from 2002 to 2013.

"The only form of competition that consistently and substantially decreases prescription drug prices occurs with the availability of generic drugs, which occurs when the monopoly period ends," Kesselheim said. "But there are a number of tactics we found that can delay entry of generic drugs or reduce their uptake."

Kesselheim and his coauthors conclude that there is a need for limiting the award and extension of these exclusivity rights, enhancing competition by ensuring timely generic drug availability, providing greater opportunities for meaningful price negotiation by governmental payers, generating more evidence about comparative effectiveness of therapeutic alternatives, and educating patients, prescribers, payers, and

policy makers more effectively about cost-effective choices.

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