The High Price of Prescription Drugs
: Challenges We Face and Possible Solutions

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Abstract

Rising prices of prescription drugs in the U.S. has been a major concern for the public for decades, leading to high accessibility barriers among the public and underlying social inequality. The reasons behind the high prices involve inelastic demand, costly patent procedures, and market exclusivity. In this paper, we studied previous reforms that focused on lowering drug prices, including MCCA, MCC, ACA, etc., and their effectiveness using historical drug prices for a few decades. Our research found that the previous interventions have not significantly changed the increasing trend of drug prices in the long term due to various limitations related to each policy. Thus, we introduced several possible solutions in the future and recommended reference pricing and value-based pricing built on exclusivity mitigation for the short term and long term respectively.

1. Introduction

The increasing cost of prescription drugs has been a growing concern for patients worldwide, especially in the United States. According to a 2021 study by the RAND Corporation, prices of prescription drugs in the U.S. are 2.4 times higher than the average prices of nine other nations including Austria, Australia, Belgium, Canada, Germany, Japan, Sweden, Switzerland and the United Kingdom.[1]

U.S. Drug Prices in International Comparison

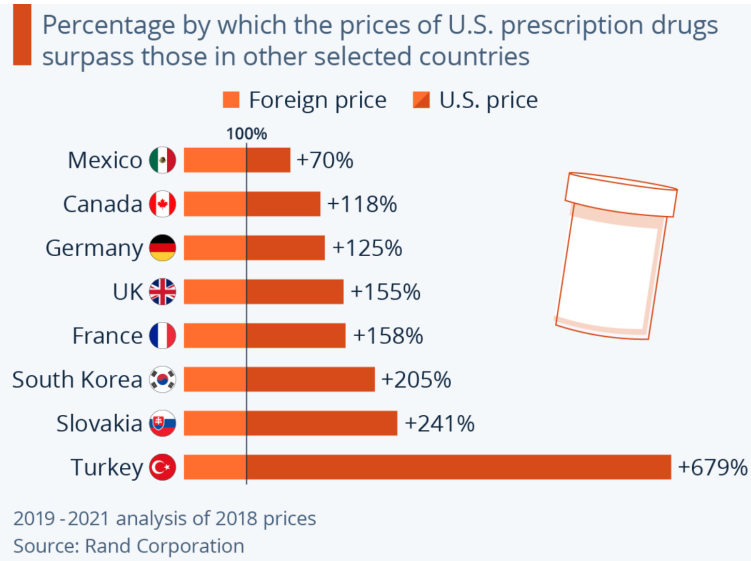

Figure 1

The reasons behind such sky-high prices of drugs are closely related to the supply and demand of the market. First, from the supply side of the market, the release of new drugs takes years to achieve: the patent procedure is significantly time and cost consuming. Thus, the pharmaceutical companies have to charge a high price to cover the cost. After release of new drugs, the market exclusivity of the drugs would be protected by monopoly rights awarded upon FDA and by patents. Therefore, the drug market lacks enough competition to drive down the price. Also, in order to encourage investment in innovation and medical development, pharmaceutical companies should be guaranteed a certain amount of profit within a reasonable range. Second, due to the necessity of prescription drugs , the patients' demand is extremely inelastic. The targeted patients, sometimes with long-term disease, need to pay for the prescription drugs over a long period of time regardless of the high prices since they have very few substitutions to treat their disease. In order to increase medicine accessibility and reduce drug prices,

[1] https://www.pgpf.org/blog/2022/11/how-much-does-the-united-states-spend-on-prescription-drugs-compared-to-other-countries#:~:text=According%20to%20a%202021%20study,Switzerland%20and%20the%20United%20Kingdom

generic drugs are permitted after the exclusivity period, but the procedure of releasing them into the market requires numerous business and legal strategies. Although some of the generic substitutions of brand name drugs are currently available on the market, the price of alternative generic drugs can still be unaffordable by low income patients.

Because of the high price of prescription drugs, patients are struggling to pay the bills. Even patients with insurance and decent income are sometimes forced to make hard choices-tapping savings, taking on new debts or even forgoing treatment. Thus, lowering drug prices can be critical to increase social welfare. Joseph Walker (2015) mentions that Due to the high out-of-pocket costs, a large portion of the population are not able to pay for the drugs and they all deserve to obtain medical support as much as others.[2] The study, published in JAMA Network Open and reviewed by the US Centers for Disease Control and Prevention, looked at how dramatic increases in the prices of anti-infectives affected the overall cost of healthcare and patients' access to treatment. Analyzing around 89,000 cases between 2010 and 2018, the research revealed that a hike in the cost of antiparasitic drugs led to a significant decrease in the amount of patients receiving the appropriate medicine for their condition. Additionally, a standard-of-care (SoC) treatment for hookworm increased in price from $32.77 to $1,660 between 2010 and 2018, correlating with a decrease in patients receiving an appropriate drug from 43% to 28% in the same period. A SoC drug for pinworm went from $14.81 to $930, while the percentage of patients receiving appropriate treatment dropped from 81% to 28%. These results show significant causal relationships between increase in drug prices and decrease in patients accessibility.

In this paper we argue that, in the short term, external reference pricing should be proposed to lower the drug prices and, in the long run, the value-based pricing should be achieved in order to establish a stable market. This paper proceeds as follows: in section 2 we examine the current level of drug prices and the previous policies. Then, we studied the limitations and outcomes of the previous policies. In section 3, we introduced other policy implications and their pros and cons respectively. And we proposed our policy recommendations in section 4 . Finally, section 5 is the conclusion.

2. Previous Policies Regarding High Prescription Drug Prices

Medical costs, especially the high price of prescription drugs, have been social problems for a long time. As of now, the government has come up with numerous policies to mitigate this issue. Those previous

[2] https://wallacehouse.umich.edu/wp-content/uploads/2016/04/Walker.pdf

policies could give insights into future policies. In this section, therefore, we will review the primary previous policies that tried to solve the problem.

2.1 The Medicare Catastrophic Coverage Act (1988)

The Medicare Catastrophic Coverage Act (MCCA) was enacted in 1988, aiming to improve medical care for the elderly and disabled. MCCA expanded Medicare benefits to include outpatient drugs and limit enrollees' copayment costs for other covered services. It also provided progressive premiums with very high deductibles. This helped lower-income individuals lessen their financial burden.

2.2 Medicare Prescription Drug, Improvement, and Modernization Act (2003)

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) was established in 2003 to lower the individual financial burden of prescription drugs. MMA is quite similar to MCCA in terms of structure and purpose. The thing that distinguishes MMC from MCCA is that MMA is more focused on prescription drug prices whereas MCCA was on the general health care costs. With MMA, the elderly and the young having disabilities who are already covered by Medicare can get a prescription drug benefit. It also provides a subsidy for prescription drugs to lower-income people. MMA is assessed as a policy that formed a ground for prescription drug coverage and the modern Medicare Advantage program.

2.3 Patient Protection and Affordable Care Act (2010)

The Patient Protection and Affordable Care Act (ACA) was enacted in 2010 with three primary objectives. First, it was implemented to make more people insured. As the private insurance market is not affordable or a huge burden, especially for lower-middle-income people, ACA provides premium tax credits, and subsidies for health insurance, to households with incomes between 100% and 400% of the federal poverty level (FPL). Second, ACA aims to broaden Medicaid, lowering the beneficiary standard. Several states have expanded the qualified income level for Medicaid up to 138% of the FPL. Lastly, ACA tries to decrease universal healthcare costs, supporting innovative medical systems.

2.4 Prescription Drug Pricing Reforms (2022)

After several failed legislative efforts over the past decades, in August 2022, Congress enacted prescription drug pricing reforms as part of the Inflation Reduction Act. The law includes the most profound policy changes to prescription drug pricing since outpatient prescription drug coverage was introduced to Medicare (Part D) in 2003, including allowing Medicare to directly negotiate prices for certain drugs, limiting price increases, and reducing out-of-pocket costs for Part D beneficiaries.

2.5 Challenges Faced by Previous Reforms

Even though the government has implemented different policies to handle the high prescription drug prices, they have not been significantly effective. In this section, we will address the drawbacks of each previous policy and also the shortcoming that all four previous policies are sharing.

2.5.1 MCCA

MCCA was implemented under weak public finance. Because of the unstable government's financial state, the beneficiaries of MCCA had to bear the additional payment to finance the new coverage. This, of course, generated a huge disagreement on MCCA. To make matters worse, the lack of comprehensive information and clear communication facilitated the criticism of this policy. As a result, MCCA was repealed a year later from the enactment.

2.5.2 MMA

MMA is problematic as it lowers the bargaining power of the government. It is the insurers who negotiate the drug pricing with the drug manufacturers under MMA. This mechanism prevents the government from directly negotiating with the drug companies and eventually weakens the government’s influence on drug pricing. Weakened government bargaining power results in increased social costs for health care as the government is in charge of Medicare, Medicaid, and other public healthcare programs.

2.5.3 ACA

ACA has two major drawbacks, efficiency and the loss of company-sponsored insurance. First, the ACA could be inefficient for some people as the plans are not personalized. For instance, people who do not need maternity care may pay for a plan including maternity care because one cannot tailor the plan based on their needs. Second, the ACA may cause the loss of company-sponsored health insurance when some firms find that it is more cost-effective for them to encourage the workers to be insured by ACA, not providing employee health plans. This unloads the private sector’s financial burden on the government.

2.5.4 Prescription Drug Pricing Reforms

Prescription Drug Pricing Reforms are expected to have an optimistic prospect compared to the three previous policies. According to the cross-sectional study by Benjamin N. Rome, Sarosh Nagar, and Alexander C. Egilman (2023), the Inflation Reduction Act of 2022 will likely result in substantial savings in the first 3 years for many high-spending drugs. However, there are a couple of expected problems. The

study also shows that simulating the drug price negotiation provisions in the Inflation Reduction Act of 2022 revealed various limitations, including strict selection criteria and the potential for drugs to become ineligible for negotiation during the 2 years between selection and prices taking effect.

Currently, the 2022 Inflation Reduction Reform has been enacted and received positive anticipation from the public. The Congressional Budget Office initially estimated that these provisions would save the federal government $288 billion over 10 years. Benjamin N. Rome and his colleagues found that Among the 37 out of 40 selected drugs in this reform, estimated net Medicare spending from 2018 to 2020 was $55.3 billion; spending at ceiling prices would have been reduced by an estimated $26.5 billion, which represented 5% of estimated net Medicare drug spending during those 3 years.

2.5.5 Overall Improvements

Meanwhile, what all of the previous policies share is that they are not directly dealing with high prescription drug prices. Most of the prescription drug coverages that have been implemented up till now just remained in expanding the existing Medicare or Medicaid programs. The key factor of the problem of high prescription drug prices is, however, market exclusivity generated by different reasons. Therefore, the previous policies are too superficial to solve the intrinsic cause. Moreover, this creates a further problem of a blind spot as selective welfare policies are mainly concentrating on the elderly and disabled.

2.6 Empirical Evidence

Given the goal of the previous reforms, we would anticipate market responses to the acts. However, the effect was not as significant as we believed. By comparing the CPI between the price of medical care and the average of all other items. Medical care prices started out running the average of other daily products since as early as 1985. Then, the gap between medical cost and other costs has kept increasing for the past few decades. This increasing trend could partially contribute to the 1980 patent law(Bayh–Dole Act) and the development and marketization of new drugs, such as antibiotics (1940 – 1962), over the decades.

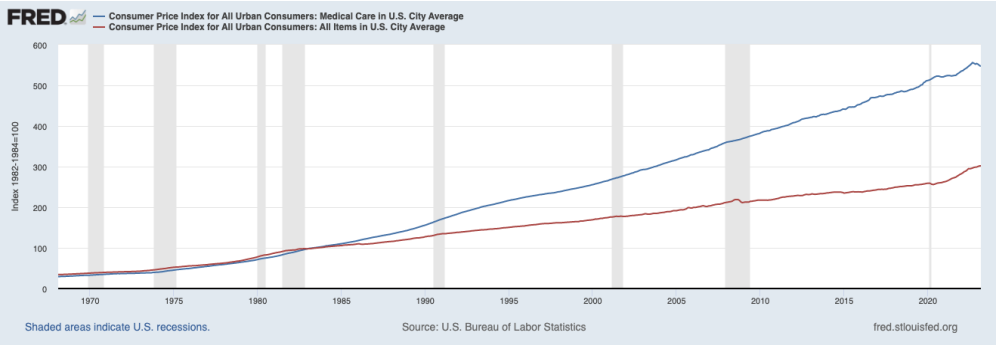

Figure 2

The similar trend is also shown particularly on prescription drugs. According to the data from the Congressional Budget Office, the price of prescription drugs has been increasing significantly since 1980. There was a slight decrease in the price from 2008 to 2014 possibly caused by the reforms in 2003 and 2010. However, this decreasing trend only existed shortly and the price of drugs increased even more right after 2014 and reached about $1,100 per capita spending. Thus, the previous reforms before 2003 failed to lower the price of prescription drugs or slow down the increasing trend effectively. Although the price decreased temporarily during the later two reforms, the effect did not last long.

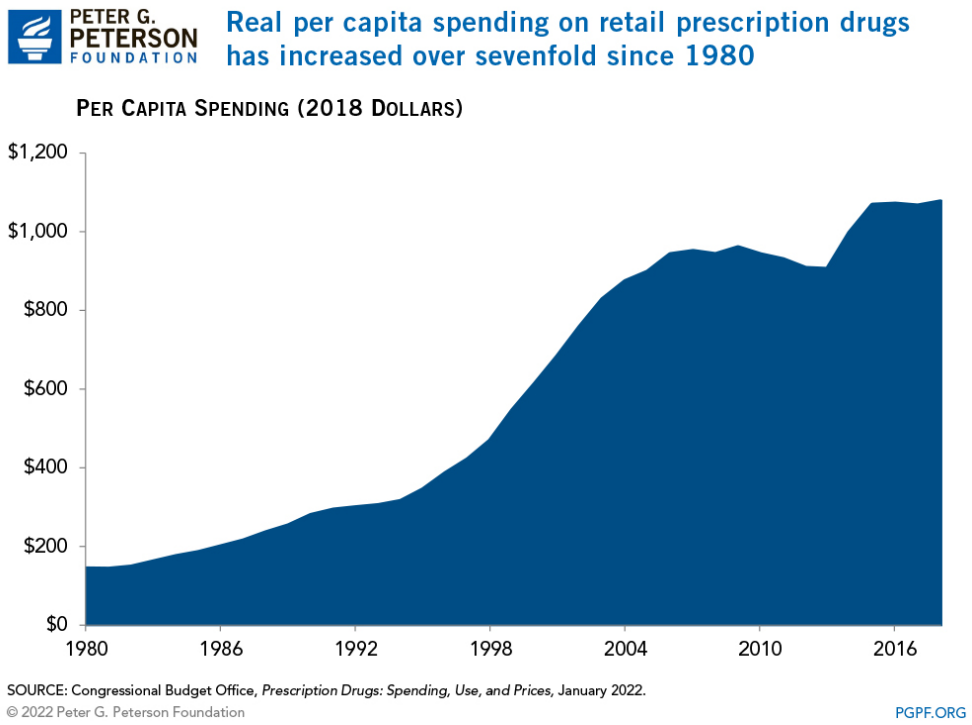

Figure 3

3. Policy Implications

As we have discussed above, it is obvious that prescription drug prices are so high, especially considering the drugs are medical resources that are basic necessities for human life. Unfortunately, there are no single policies that previously intervened in this issue firsthand. Hence, we suggest four potential policies that could possibly alleviate the problem.

3.1 Exclusivity Mitigation

Exclusivity mitigation is alleviating monopolistic features of the prescription drug market based on the market principle. This can be achieved by introducing biosimilar substitutions, generic alternatives, and more stringent requirements for the award and extension of patent rights.

This potential policy is beneficial because this tries to solve the core cause of the problem. Also, this would minimize the side effects of government intervention as it is worked by the basic market principle of supply and demand. There are, however, a few concerns as to implementation. Although the availability of generic drugs after the exclusivity period is the main means of reducing prescription drug prices in the US, access to generic drugs may be delayed by different unpredictable business and legal strategies. Also, if consumers' preference for brand-name drugs over generic drugs (Shrank et al., 2009) does not change along with this policy, the effects of lowered drug prices would be insignificant.

3.2 Reference Pricing

Reference pricing is comparing a drug to other drugs having the same ingredients or clinical effects. There are two branches of reference pricing, including internal reference and external reference. While internal reference pricing is comparing a drug to other drugs within a country, external reference pricing used by most EU countries is comparing them internationally. As we are with a problem of the US domestic prescription drug prices, our focus would be on the external reference pricing.

Reference pricing gives a clear advantage of determining a price limit with relatively reasonable standards when the government sets the comparison targets to the countries based on the similarities in terms of GDP per capita, living costs, health insurance system, etc. On the flip side, there is still room for controversies. First, it is difficult to figure out the unrevealed prescription drug pricing mechanisms, for example, rebates and discounts, of different drugs in different countries. Second, there is a possibility of a drug shortage caused by delayed drug launches or no launch at all, especially in countries with a lower

willingness to pay for the drugs. This is because this approach may encourage manufacturing companies to register first in countries with the highest willingness to pay as the firms would be incentivized to prevent other countries from adjusting the prices downwards. We know that registering in different countries is not a quick task and it takes some time and effort to do that. However, we cannot ignore this kind of possibility because we are living in a globalized world with an increasing number of multinational companies as well as it could be a serious ethical issue.

3.3 Profit Control

Instead of directly interfering in pricing strategies of companies, rate-of-return regulation can mark a profit limit. In the UK, profit control uses caps (to a maximum of 29.4%) as a measurement, which means that a company can adjust the price of new drugs within its portfolio as long as the overall profit does not exceed the cap. Firms that exceeded allowed profits were required to forfeit the excess profits or lower prices; firms earning <75% of their profit target could raise prices.

This type of regulation is implemented in order to achieve reasonable prices while safeguarding the profitability of the innovative pharmaceutical industry. However, it is difficult to determine the total profit of pharmaceutical companies in practice and negotiation about the profit limit requires more information and research. Thus, the effectiveness of this policy is still inconclusive.

3.4 Value-based Pricing

Value-based pricing determines the price of each drug, taking into account the value of the drug comprehensively. As the value is not limited to the present value or health value, the value-based pricing model also includes the socioeconomic benefits of a drug. Estimating these benefits is conducted by developing outcome-based sophisticated compensation models. Once we get the value of the drug utilizing the models, a drug is priced proportionately to the added value in terms of the quality of life, life years saved, or tumor shrinkage.

Value-based pricing seems to be the most precise and reasonable pricing for prescription drugs. Moreover, this would increase not only the value of a drug per monetary unit spent on health care but also innovation in relevant areas. However, it is difficult to gauge the socio-economic benefits of each drug precisely because of asymmetric information between the government and manufacturers as well as the unpredictable features of the future. Also, it would take a lot of time and effort to establish methodologies for value-based pricing as there are no standardized practices in this field.

4. Policy Recommendation

Each of the potential policies has different advantages and shortcomings. Therefore, we recommend policies for two timeframes with the most suitable ones.

4.1 Short-Run

In the short term, external reference pricing would contribute to decreasing current high prices. Compared to other policies, reference pricing is applicable immediately. This is because, under the 'referencing' method, the government can adjust the prices of prescription drugs without setting a whole new pricing plan. Also, external reference pricing would be pretty reasonable as we have looked at previously. This can lessen the validity of the opposition of the damaged party due to this policy implementation.

4.2 Long-Run

Meanwhile, reference pricing may risk the stability of medicine supply in the long run as it is described in the policy implications section. Therefore, we propose the combination of value-based pricing and exclusivity mitigation in the long run.

Value-based pricing would take a lot of time and effort to be implemented because the government needs to make principles to value drugs. The government also has to negotiate with drug manufacturers to get sufficient drug information which will be the evidence of valuation. However, once these conditions are met, we expect this pricing method would produce highly positive effects such as innovative growth in the drug industry.

The thing is that value-based pricing should be accompanied by exclusivity mitigation. Implementing the value-based pricing alone would bring insignificant changes as this policy can achieve its full potential in a competitive market rather than a monopolistic market. There will be, of course, political difficulties affected by lobbying or so in alleviating exclusivity. However, a recent study (Wouters et al., 2022) is indicating that there is no association between unreasonably high drug prices and R&D costs, refuting a conventional argument of pharmaceutical companies.

5. Conclusion

This paper presents the current situation of high prescription drug prices with supporting empirical evidence and examines the pros and cons of related policies in the past and potential policies in the future. It is shown by data over the past decades that previous reforms before 2022 have not been successfully

lowering the price of prescription drugs and the effectiveness of current Inflation Reduction Act, though received optimistic responses, is still not conclusive. According to this situation, we suggested two potential recommendations: external reference pricing for short term and value-based pricing built on exclusivity mitigation for the long run to intervene with the price directly and set a reasonable price ceiling. However, in order to achieve better efficiency in drug markets, further research and data collection are still needed. We believe that the government would make progress given the seriousness of the matter and the huge expected utilities in the future.

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