Testimony on:

Promoting Competition To Lower Medicare Drug Prices

Douglas Holtz-Eakin

President, American Action Forum*

U.S. House of Representatives, Committee on Ways & Means

Subcommittee on Health

March 7, 2019

*The views expressed here are my own and not those of the American Action Forum. I am indebted to my colleagues Christopher Holt and Tara O'Neill Hayes for their assistance.

Chairman Doggett, Ranking Member Nunes, and members of the committee, thank you for the opportunity to testify today on the matter of drug prices. I hope to make four basic points.

1. The term "rising drug costs" is riddled with ambiguity; list prices, net prices, out-of-pocket prices, development costs, and total spending on drugs have displayed very different patterns over time.
2. There is rising demand for pharmacological therapies driven by an aging population, chronic disease, and the development of specialty drugs.
3. In the face of rising demand, the only way to reduce prices efficiently is to increase supply and heighten competition.
4. In thinking about policy actions, it is important first to recognize existing policies that exacerbate price increases. Unfortunately, several popular proposals avoid this step and are unlikely to be beneficial.

Let me discuss these further.

Introduction

Over the past several years, the public's attention has increasingly been focused on the cost of health care, and specifically the contribution of prescription medications to those costs. With 55 percent of the U.S. population using prescription drugs as of 2017,[1] drug pricing concerns are widespread, fueled by expensive sticker prices on certain new medications, the pricing revelations at Turing Pharmaceuticals and other companies, and the EpiPen episode. These concerns are driving policymakers to consider addressing drug prices through legislation and regulation. Policymakers, however, should first clearly identify the precise problem they're trying to address.

Identifying the Problem: Patterns in Drug Costs

There is little consensus about the meaning of the term "rising drug costs," making it difficult to determine if there is an actual policy problem, its size, or its scope. The first step in identifying whether there is a problem is to differentiate between prices, costs, and spending, which are related but not identical.

For example, "rising drug costs" might refer to a narrow definition focused on the sales prices (or "list price") set by drug developers and manufacturers. Alternatively, the problem might not be with all drugs, but instead the high prices of some drugs. Finally, the problem may be the increasing cost of prescription drugs borne by individuals at the pharmacy counter, which has resulted from an increase in the prevalence of high-deductible health plans.

Rising drug costs could also mean an increase in overall prescription drug expenditures, whether in dollar figures or as a percentage of National Health Expenditures (NHE).

Because spending is a function of both price and quantity, this could result from increased utilization due to rising national reliance on prescription drugs or broader access to them.

Pharmaceuticals as a Share of National Health Expenditures

The first important fact to consider is that prescription drug spending as a percent of NHE has remained steady at about 10 percent since 2000, the same percentage it was in 1960. There was a dip in prescription drug spending as a share of NHE in the years between 1960 and 1980, as advances in technology and expanded insurance coverage of hospital visits contributed to a shift in NHE towards hospital stays.[2] In the 1980s, that trend began to reverse as new pharmaceuticals became widely available for the treatment of many of the most prevalent diseases in American society. The availability of advanced pharmacological treatments is highly correlated with reduced expenditures for hospitals and other health professionals.[3] As pharmaceutical growth then settled to roughly the same levels as in the 1960s, so did other NHE categories.[4] Viewed from this national perspective, there appears to be little support for a radical rise in drug spending in the data, although national averages can mask the variance among subpopulations and the most current NHE data is more than a year old.

Drivers of Drug Spending

To the extent that drug expenditures are increasing or will begin to increase in the near future, a key factor is utilization. Annual growth in pharmaceutical spending in November 2018 was 5.1 percent,[5] but annual pharmaceutical price growth was only 0.6 percent.[6] On a per capita basis, real net spending has grown by only 1 percent since 2007 and actually declined by 2.2 percent in 2017.[7]

Still, Americans are getting older, living longer, and are increasingly burdened with chronic disease. As of this year, 60 percent of the United States' adult population had been diagnosed with at least one chronic health condition, and 40 percent had two or more chronic conditions.[8] Managing these chronic conditions is an expensive proposition that relies primarily on medication. Eighty-six percent of all health care spending is for patients with one or more chronic disease; 98 percent of Medicare and 83 percent of Medicaid spending goes toward providing care for the chronically ill.[9,10] Specifically, over 75 percent of U.S. health care spending goes toward treatment of chronic disease.[11] As these trends continue, the financial burden of maintaining a high quality of life with chronic conditions will inevitably disproportionately increase the growth of pharmaceutical health care spending.

Drivers of Drug Prices

Developing new treatments is an expensive prospect in terms of both capital and time. A Tufts University study in 2016 found that the average cost for each drug successfully brought to the market is nearly $2.9 billion.[12] Data from the Organisation for Economic Co-operation and Development also shows that the amount of spending per new drug approved has been growing for decades.[13] It takes an average of 15 years from the time a drug developer first begins testing a new formula until the Food and Drug Administration (FDA) approves it.[14] Only 1 in 1,000 drug formulas will ever enter pre-clinical testing, and of those, roughly 8 percent will ultimately receive FDA approval.[15]

Additionally, the last decade has seen a significant shift toward the use of "specialty drugs." While there is no precise definition of a specialty drug, this term typically refers to drugs with at least one of the following characteristics: requires special handling, must be administered by a doctor, requires patient monitoring or follow-up care, or is used to treat complex, chronic conditions.[16] As a result, these drugs tend to be quite expensive.

In fact, by 2016, about half of the top 80 most expensive drugs nationally were specialty drugs, and that number is increasing annually.[17] In 2010, the United States spent just over $11.5 billion on the top 25 specialty drugs. By 2017, net spending on specialty medicines reached $151 billion, accounting for 46.5 percent of all expenditures on medicines, despite accounting for just 2 percent of the volume.[18] Since specialty drugs are often more expensive to develop and typically treat small patient populations with very specific and otherwise untreatable diseases, they tend to have higher prices. Over time, the cost of new specialty drugs per patient will likely remain high as the target population for each new drug will grow smaller with the development of treatments for less common diseases.

List Versus Net Prices

An important aspect of the discussion is the difference between list price and net price. List prices for brand-name drugs, on average, have increased between 7 and 13.5 percent over the past six years, yet the average net price of these drugs has grown between 1.9 and 4.7 percent, with the rate of increase declining..[19] In fact, price growth for prescription drugs over the course of 2018 was at its lowest rate since 2013, and even dipped into negative territory between December 2017 and early 2018.[20] So while the average list price of brand name drugs rose 35 percent between 2013 and 2017, average out-of-pocket (OOP) costs for those drugs remained unchanged at $30.33.[21] Similarly, generic list prices rose 7 percent during this time period, but patient OOP costs declined more than 9 percent as a result of discounts and rebates. The increasing difference between list and net price points to the growing use of discounts and rebates. Understanding the role of these incentives in price determination is an area worthy of careful consideration to ensure resources are being allocated as desired.

Out-of-Pocket Prices

From a patient perspective, many anecdotally report that OOP costs are climbing and the increased frequency of high-deductible health insurance plans is cited as the reason. But the data show that average patient OOP costs at the pharmacy counter have actually declined since 2013. Nearly one-third of all medicines were available in 2017 for zero OOP costs, and 97.5 percent were available for $50 or less, with the average OOP cost equaling $8.69. Only 2.5 percent of prescriptions filled had a co-pay of more than $50. But for the small share of very costly drugs, the expense adds up fast: 3.4 million prescriptions (0.1 percent of all prescriptions filled in 2017) had an OOP cost of more than $500, with an average cost of $1,502; total OOP expenditures for these drugs was $5.2 billion.[22] It is likely also true that a number of prescriptions that would have cost at least that much were never filled because the patient simply could not afford it (or chose not to spend the money). The abandonment rate for brand-name drugs reached 21 percent in 2017.[23]

A Review of Possible Solutions

Following the leading principle of the Hippocratic Oath, policymakers should "first, do no harm." The myriad mandatory discount programs and industry taxes collectively result in higher list prices and cost-shifting to the private market as companies look for ways to offset the lost revenue. These programs don't reduce the cost of the drug; rather, they distort the health care market (beyond just the prescription drug market) and force some to pay more so others can pay less.

There are a number of proposals that are frequently mentioned as ways to reduce drug prices. A bit of reflection suggests that few are likely to be successful.

Government Negotiation

Some have argued that the best way to reduce drug costs, in Medicare Part D or otherwise, is to allow government negotiation. Although government negotiation is expressly prohibited in Part D, the program is rich with price negotiations. In fact, the Part D plan sponsors negotiate directly with drug manufacturers, and this is a cornerstone of the program's success. Part D beneficiaries have access to 27 different plans, on average, enabling individuals to choose a plan that is tailored to their needs.[24]

Government negotiation of drug prices could only be effective if the government were willing and able to impose a drug formulary (like the Part D plan sponsors already do) and to restrict access to medicines for which the price is "too high."[25] Doing so, however, would fundamentally change the Part D program. The government would have to impose a single formulary in order to leverage the negotiating power advocates claim it has, which would eliminate the key differentiator between plans. Suddenly, beneficiaries' choices would drop from 27 plans to 1. Beneficiaries would no longer be able to shop for the plan that's best for them; rather, they would have to simply hope the government was able to negotiate a good deal for the drug(s) they need.

Compulsory Licensing

Others have argued instead for allowing compulsory licensing of patented drugs when an acceptable price cannot be agreed upon. Compulsory licensing allows a government to authorize the use of a patent and the information contained within without the consent of the patent holder. Essentially, the government would enable another entity to manufacture the drug by providing access to the science needed to recreate the drug. Doing so would allow the drug to be manufactured at a much lower cost since no investment in research would be needed, thus allowing it to be sold more cheaply.

The critiques of this approach are both philosophical and practical. Compulsory licensing is government theft of intellectual property. The promise of the protection of intellectual property is a necessary cornerstone for encouraging innovation. It is the very reason we have a patent system and protections and benefits for such patents in the first place. Accordingly, the president and members of Congress on both sides of the aisle are strongly opposed to the theft of American companies' intellectual property by foreign companies and even foreign countries. Policymakers clearly recognize the extent of the damage that could ensue from such a threat. The threat from compulsory licensing is no different.

Allowing the theft of intellectual property by our own government could have a chilling effect on innovation. Policymakers must carefully weigh the desire for a lower price for treatment of today's disease against the cost of potentially fewer treatments for tomorrow's disease.

Part B Inflation Rebate

Last year, legislation was introduced to require drug manufacturers to pay a rebate for any drug covered under Medicare Part B for which the drug's price increased beyond the rate of inflation. This would be similar to the existing requirement in the Medicaid Drug Rebate Program. Previous analysis by the American Action Forum has found that price increases have been largely correlated with the imposition or expansion of mandatory rebates and taxes.[26] Further, any penalty on increasing prices will naturally encourage higher launch prices, which would certainly not be ideal.

Drug Re-importation

Drug companies don't want their drugs sold for the lower prices available in other countries; of course, they often sell at that low price because a low price is better than nothing. They will most likely not sell excess drugs to those countries to allow for a supply to be available for re-importation into the United States. And those countries, not having any excess supply, are going to provide the limited number of drugs they do have to their own people before they allow them to be sold back to the United States. Even if the United States were to allow drug re-importation, the economics make it very unlikely that it would have any impact on the availability of cheaper medicines in the United States. And that's saying nothing of safety concerns, which are legitimate.

International Reference Pricing

The Trump Administration recently proposed establishing a demonstration program for drugs covered through Medicare Part B, under which reimbursement would be tied to an International Pricing Index (IPI). Unfortunately, this is not likely to reduce prices, and in fact, could result in significant undesirable repercussions.

The 14 countries that the Centers for Medicare & Medicaid Services (CMS) has proposed referencing in this IPI model, on average, have access to only 48 percent of the new drugs developed in the past eight years, and it took an average of 16 months after their initial global launch for those drugs to become available in those 14 countries. The United States, on the other hand, has gained access to 89 percent of new medicines within three months.[27]

If this model were adopted and applied to all Part B drugs, revenues would be reduced approximately $9 billion per year based on the most current expenditure levels. Given that the cost to develop a new medicine is estimated to be $2.9 billion, as many as three fewer new medicines may be developed each year as a result of this model if drug manufacturers are unable to recoup these lost revenues in other markets.

Also of concern are the indirect effects and implications of adopting a reference pricing model. Of the 14 countries under consideration for this reference pricing model, 11 use reference pricing themselves to control their prices. Between four and six of these 11

countries reference each of the following countries in determining their own price: Cyprus, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia, and Spain. By referencing the price of drugs in countries that reference the prices in other countries, we would indirectly be referencing the prices of those other countries. The average gross domestic product (GDP) per capita in these countries listed was $18,685 in 2017, while the GDP per capita in the United States was $59,532—more than three times greater. The estimated age-standardized mortality rate for all cancers in these countries is 123.47, compared with a rate of 91 in the United States. The average life expectancy in these countries is nearly a year shorter than that of the United States. It is not appropriate for the United States to reference the prices paid in countries so different than ours.

Adopting the non-market prices of other countries, and thus the punitive and authoritative policies used to obtain those prices, will likely also mean adopting for American patients similar levels of restricted access to new medicines as experienced in other countries. Worse yet, this demo may result in new medicines never being developed in the first place. Americans highly value their access to and choice of new treatment options. The reduced innovation that will likely occur as a consequence of the reduced manufacturer revenues that will result from this model will have significant ramifications. Further, referencing the prices paid for drugs in countries that do not adequately reflect the value of medicines is inconsistent with the administration's goal of adopting a value-based payment system.

Finally, this model will undermine American trade policy, which may have repercussions far beyond the pharmaceutical industry. The United States should instead work to strengthen intellectual property rights in other countries and fight compulsory licensing in trade agreements to end the coercive practices that allow countries to force manufacturers to provide their drug for less than it's worth; this is the only way to get other countries to pay more so that we may hopefully pay less without risking reduced innovation.

There are, however, some proposals that would be successful in reducing prices.

Competition and Increased Supply

History has proven the best way to reduce the price of a good for which there is growing demand is to increase its supply through competition. For drug pricing, that means bringing generics and biosimilars to market to compete with brand-name drugs.

A now-classic example of this phenomenon is the Hepatitis C treatment, Sovaldi, which contributed over $3 billion to 2014 expenditures alone.[28] While the drug was quite expensive, it is important to note two things. First, Sovaldi—and its eventual competitors—provided a cure for what had been up until that point a costly-to-manage chronic disease. Second, as competitors came into the market, the price of Sovaldi was cut in half. Where there is competition, prices come down.

The FDA is doing its part by approving a record number of generic drugs and biosimilars.[29] But other barriers to unlocking robust market competition remain.

Barriers to Entry

Manufacturers of innovator drugs understandably want to protect their market share as long as possible. As discussed, bringing a drug to market is a rather risky and expensive

endeavor, and investors need the promise of a formidable profit to be incentivized to make that investment. And there can be no generic without first having the expensive innovator drug. The needs of the investors to receive a return, however, must be balanced with the needs of the consumers and taxpayers in order for the market system to remain sustainable. There are obvious incentives for brand-name manufacturers to extend the length of their market exclusivity through various means. Congress can scrutinize the opportunity to create entry barriers, such as brand-name manufacturers allegedly abusing the REMS system and, if appropriate, legislate to help even more generics come to market quickly.[30] (One such example is the CREATES Act.)

Legal Enforcement of Competition Policy

Another challenge is the case of single-source generics. Often, once a generic drug has been on the market long enough, it acquires enough of the market share that the brand-name manufacturer stops producing its version of the drug. In many cases, the price reaches a low enough point that other generic competitors also exit the market, leaving a sole manufacturer. In some high-profile cases we see what amounts to abuse of monopoly power—that sole manufacturer taking advantage of its position and dramatically increasing its price once there is no more competition and consumers have no choice but to purchase the now high-priced drug. In these cases, it should be treated as the abuse that it is and prosecuted where appropriate.

Prosecuting such monopoly abuses may require new authority for the Federal Trade Commission (FTC). The FTC's mission is "to prevent business practices that are anticompetitive or deceptive or unfair to consumers." The FTC notes that it has limited authority to take action against a company that has drastically raised the price of a drug, depending on the reason for the increase. In January 2017, FTC Commissioner Maureen Ohlhausen wrote, "Standing alone, a 'high' pharmaceutical price is not an antitrust violation if it simply reflects a legally obtained intellectual property right."[31] Antitrust laws aim to prevent the stifling of competition; if a company that is not even in the pharmaceutical business purchases one that is (a non-competitor) and raises the prices of its product, it has not in any way decreased competition. In fact, this is exactly the type of behavior that should encourage new market entrants; when competition resumes, the price should fall.

Congress must carefully consider the potential ramifications of authorizing a government entity to prohibit a private company from setting the prices of its products. As Ohlhausen wrote in February 2017, "Antitrust is about protecting the process, not guaranteeing a particular result at a particular time."[32]

Modernizing Medicare Part D

The Part D program is also in need of reform. Though the program has generally been quite successful, recent trends detailed here have highlighted the need for structural reforms. The current program structure—namely the minimal liability on plans for high-cost enrollees (particularly after the changes made by the Bipartisan Budget Agreement of 2018),[33] the coverage gap discount program and the counting of those manufacturer rebates toward a beneficiary's True Out-of-Pocket (TROOP) calculation, and the existence and nature of the risk corridors—does not incentivize plans strongly enough to control the

cost of high-cost drugs and even allows plans to shift more costs to the federal government beyond what was intended.[34]

Medicare Part D reinsurance expenditures have grown rapidly for the federal government over the past several years, primarily because of a significant increase in both the number of beneficiaries reaching catastrophic coverage and the costs that each of them incur. This rapid growth has caused reinsurance expenditures to increase from less than one-third of the federal government's overall subsidy of the Part D program in 2007 to more than two-thirds of the subsidy in 2016. Further, a recent investigation by *The Wall Street Journal* found that plan sponsors have leveraged the program's risk corridors to contain their losses and increase their profits, resulting in $9.1 billion in extra subsidies.[35]

One way to realign incentives is a restructuring of the program's benefit design proposed in a recent American Action Forum study: Increase insurer liability in the catastrophic phase to roughly 70 percent while simultaneously reducing the government's liability to 20 percent, and move the drug manufacturer rebate program from the coverage gap to the catastrophic phase to cover the remaining costs. These changes will significantly increase the incentive for both insurers and drug manufacturers to control costs. Further, provide beneficiaries with true financial protection by imposing an OOP cap. Plan sponsors and beneficiaries will also benefit from a simplified benefit structure since the coverage gap will be eliminated and beneficiary co-insurance will be held steady at 25 percent above the deductible until reaching the catastrophic threshold. Such reforms should encourage behavioral changes that reduce overall program costs for all stakeholders.

Encouraging Use of High-Value Drugs by Reforming the Medicare Part B Reimbursement for Physician-Administered Drugs

CMS noted in its proposal to reform Medicare Part B reimbursement for physician-administered drugs that the current add-on payment (an additional six percent of the Average Sales Price of the drug) made to providers may unintentionally encourage use of high-cost drugs over potential lower-cost alternatives. Whether a perverse incentive is being exploited or not, the current methodology for determining the amount of the add-on payment does not seem to match its intent. As a result, CMS is looking to replace the current method for calculating the add-on payment; these changes, however, would only be possible administratively through the implementation of a demonstration program through the Center for Medicare and Medicaid Innovation (CMMI).

The add-on payment should reimburse providers for the cost of handling, maintaining, and preparing the drug as well as any costs associated with acquiring the drug, such that the provider is financially neutral with regard to which drug to use, allowing them to make the best decision for their patient.

A separate payment is also made to cover the cost of actually administering the drug to the patient. While providers should of course be paid for their labor, there is a significant discrepancy in these payments when paid to a provider in a physician's office who is reimbursed under the physician fee schedule compared with reimbursement to a provider in a hospital outpatient department (HOPD) made under the Outpatient Prospective Payment System. The difference in reimbursement can be 100 percent, which not only

increases Medicare's expenditures, but also results in patients having to pay twice as much in coinsurance, simply because of a difference in where the care is received and who owns the facility. Congress and the administration should continue working to ensure site neutral payments and eliminate the overpayments to HOPDs.

Eliminating the Safe Harbor for Drug Rebates

Drug manufacturers typically provide significant rebates for drugs provided at the pharmacy counter (averaging nearly 30 percent in Medicare Part D), especially for drugs with competing alternatives. These rebates are most commonly paid to insurers (or pharmacy benefit managers [PBMs] acting on their behalf) in exchange for preferred placement on the insurance plan's drug formulary. Preferred placement makes it more likely the patient will take that drug than another because it will be placed on a lower tier with lower cost sharing. The PBMs, however, do not uniformly share those rebates with patients when they pick up their medicine at the pharmacy counter. Instead, the rebates are to a degree used to collectively and uniformly reduce all of their enrollees' premiums.

The Trump Administration recently proposed eliminating the existing safe harbor protection for drug rebates from manufacturers unless those rebates are passed on directly to the patient at the point of sale. This would lead to significant change from the current drug pricing and insurance structure.

If such a proposal were implemented, the economics show the boundaries of the implications. At one end of the spectrum, drug manufacturers and PBMs could agree on a negotiated price that is the same as the current net price. This would provide the same net cash flows to the drug manufacturer, the PBMs, and implicitly the insurers.

This outcome has important implications. Beneficiaries would be responsible for less of the cost of their therapies, while PBMs and manufacturers are in the same economic position. By definition the cost of the change will be shifted to prescription drug plans. It is a matter of logic and actuarial analysis that they will be forced to raise premiums enough to offset this new cost.

As a matter of insurance policy, this is the "right" outcome. The broad population would bear modestly higher premiums to offset the costs of the drugs for a small, expensive population. That is the nature of insurance.

Of course, there are a myriad of other possible outcomes. This includes the negotiated price between manufacturers falling below the current net price (a "list price" reduction) that provides cash flows sufficient for PBMs and prescription drug plans to retain their current pricing. In this case, insurance premiums are unaffected.

This discussion applies to the market as a whole. To the extent that proposals affect Part D alone, and do not include the commercial market, they will tend toward the first analysis that leads to higher Part D premiums.

Address Distortions Caused by the 340B Drug Discount Program

The 340B program is in dire need of reform. While the program was created to resolve an unintended consequence of the Medicaid Drug Rebate Program, it has created its own

unintended consequences, as outlined in an analysis by the American Action Forum.[36] The 340B discount incentivizes hospitals to acquire physician practices. This consolidation reduces the number of community practices and consequently drives up the cost of care for all services at those facilities, relative to the cost of the same services provided in non-hospital-owned physician offices. Studies have shown that consolidation among hospitals and other health care facilities leads to higher costs at hospitals, often by as much as 20 percent and sometimes by as much as 40 percent.[37] Further, the program suffers from a lack of clear guidance and requirements regarding the use of savings generated. One change that could help ensure the program's discounts are passed on to the beneficiaries it is intended to serve is to reduce Medicare reimbursements for such drugs. CMS implemented such a policy in 2018, through regulation, by changing the reimbursement for Part B drugs obtained through 340B from Average Sales Price (ASP) + 6 percent to ASP – 22.5 percent.[38] Congress could codify such a change by amending the ASP calculation to include discounts obtained through 340B. Congress should reform the 340B program to restore its original intent, ensure program integrity, and eliminate the harmful market distortions caused by it. Without such reforms, the program is unsustainable and the rest of the health care market will continue to suffer.

Conclusion

Fundamentally, there is no broad prescription-drug pricing crisis. Indeed, in most instances, the system in the United States is working just fine. Rather what we face are more nuanced challenges—for example, the price of specialty drugs and biologics, which are expensive to develop and manufacture and frequently treat a limited population. In these instances, particularly with oncology drugs, it is important to make sure that the cost of the treatments correlates to the value. Remember that the goal is not low cost, *per se*, but rather high value. It is easy to have low-cost drugs; they, however, may not do much good. Conversely, it might make sense to spend more for a drug if its therapeutic benefits are high enough.

While the U.S. market has long been an environment where manufacturers are willing to invest in necessary research and development in hopes of a financial return later, more and more government regulations and taxes are reducing that incentive. Programs such as the Medicaid Drug Rebate Program and the 340B drug discount program interfere with the market incentives and shift, rather than reduce, the high cost of drug development. A more effective solution to high prices is greater competition in the supply and greater financial incentive for payers and manufacturers to keep costs and prices down.

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