

CHAPTER 5: PRESCRIPTION DRUG PRICES

OVERVIEW

The United States spends approximately \$500 billion annually on prescription drugs, more per person than any other country in the world.³⁴⁸ The *Economic Report of the President* claims that this is mostly the fault of the federal government. However, the core of the problem is a series of failures in complex and opaque markets, in which incentives for manufacturers, distributors and insurance companies often conflict with the interests of patients.

New drugs for rare diseases drive much of the overall spending. However, the law prohibits the federal government from assessing the cost-effectiveness of those medications, creating an information asymmetry that can lead to overuse of the newest and most expensive drugs. Moreover, although the United States uses generic medications at a higher rate than other OECD countries, Americans pay more for them because some companies use strategies like “pay-for-delay,” compensating other manufacturers for slowing introduction of generic drugs.

Market concentration and perverse incentives in supply chains also drive up prices. In other industrialized countries, governments negotiate drug prices, resulting in lower costs to consumers. However, Medicare is prevented by law from negotiating prices. The *Report* largely overlooks these complexities, offering few solutions that would lower costs.

IMPACT ON CONSUMERS

The growing cost of prescription drugs imposes financial hardship on millions of Americans and poses a health risk to some of the country’s most vulnerable populations. One in four Americans

who take prescription drugs reports having difficulty affording their medications.³⁴⁹

Some people cope with high costs by skipping doses. Two-thirds of Americans who did not fill a prescription in the previous 90 days did so because of cost.³⁵⁰ This figure goes up to almost 95 percent of Americans earning under \$25,000 a year. In a 2016 international survey of adults, insured Americans were seven times more likely than people in the United Kingdom not to fill a prescription or skip doses due to cost.³⁵¹

One study found that 25 percent of diabetic patients have underused their insulin because of the cost, as the price has roughly tripled in the last decade.³⁵² Although prices do not necessarily reflect the cost to consumers, Americans pay more out of pocket than people in other countries. That is because they are more likely to lack health insurance and even those with insurance tend to be less shielded from drug prices than consumers in other countries.³⁵³

The inability to comply with recommended medical treatment, including failing to fill a prescription, skipping doses or cutting pills in half to make them last longer, has severe health consequences and can lead to higher long-term medical costs.³⁵⁴ These practices are estimated to cause 10 percent of hospitalizations among older adults and are associated with increased mortality rates.³⁵⁵ They also cost the U.S. health care system an estimated \$100 billion to \$289 billion annually.³⁵⁶

Some consumers deal with high costs by attempting to purchase medicines outside of the United States. In a 2017 survey, 12 percent of consumers reported that the cost of prescription drugs drove them to purchase medication abroad.³⁵⁷

COST DRIVERS

The United States spent an estimated \$333 billion on retail prescription drugs in 2017, which was approximately 10 percent of total health care spending, according to the latest CMS National Health Expenditure data.³⁵⁸ Including non-retail drugs, such as those administered at a physician's office or hospital, the figure climbs to around half a trillion dollars or nearly one-fifth (17 percent) of all personal health spending.³⁵⁹

Americans spent approximately \$1,000 per capita on prescription drugs in 2015—roughly 50 percent more than what Germany pays and double what the United Kingdom pays.³⁶⁰ Although some of this difference is because we often use newer, more expensive treatments, higher spending is not linked to better health outcomes. Since Americans use similar quantities and types of drugs overall, much of the cost difference has to be driven by Americans paying higher prices for the same or similar drugs.³⁶¹

The Most Expensive Drugs Drive Total Costs

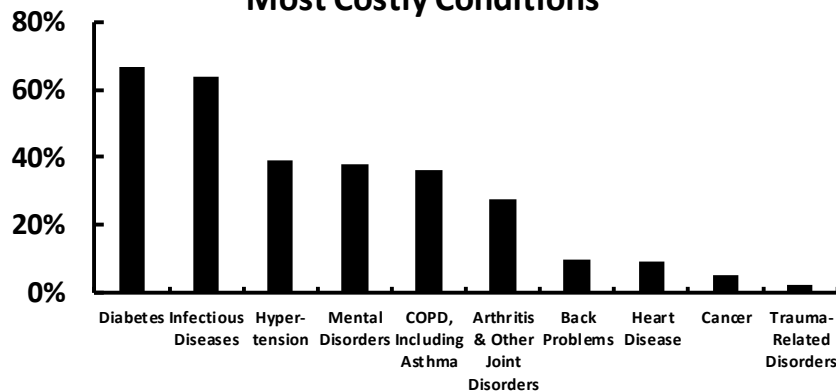
High drug prices impact all Americans, though a smaller group that uses very expensive medicines bears a growing share of the costs. Many new, innovative drug releases are for specialty drugs, which often treat chronic, complex or rare diseases and are administered by a specialist in a hospital or doctor's office. These drugs can have prohibitively high prices, running into hundreds of thousands of dollars in a single year.³⁶²

These trends force the government to concentrate on spending on fewer, costlier drugs. Just 10 drugs make up 17 percent, or \$24 billion, of all Medicare Part D spending by the government and consumers.³⁶³ The three percent of enrollees who reached the highest threshold of out-of-pocket expenses—called catastrophic

coverage—spend, on average, nearly \$3,200 out-of-pocket on their medication, over six times more than the overall average.³⁶⁴

Figure 5-1

Prescription Drugs as a Share of Spending for the Most Costly Conditions



Source: JEC Democratic Staff analysis of the Medical Expenditure Panel Survey, 2015

Note: Prescription drug expenditures do not include drugs administered by a doctor or in a hospital. COPD is Chronic Obstructive Pulmonary Disease.

For the 10 most costly conditions in the United States, private and public expenditures on prescription drugs accounted for \$227 billion, more than one-quarter (28 percent) of all outlays, even excluding the cost of drugs directly administered by hospitals or physicians.³⁶⁵ For example, the annual cost of insulin almost doubled from 2012 to 2016, reaching \$5,705 on average.³⁶⁶ Prescription drugs accounted for over 60 percent of spending on diabetes in 2015.

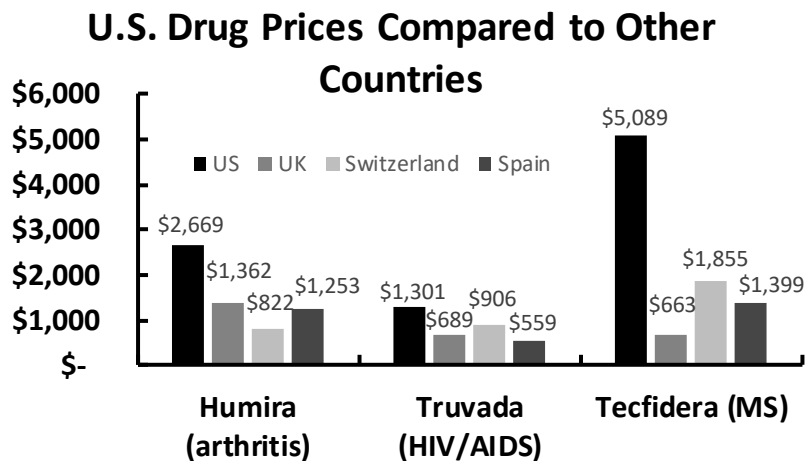
The solution to higher drug prices is not just wider use of generic medicines. In fact, data from the OECD shows that the United States already has almost the highest share of generic pharmaceutical use, comprising 84 percent of drug utilization in the United States.³⁶⁷ This suggests that at some level, incentives to use cheaper drugs are getting through to doctors and patients. It also suggests that cost differences are being driven by other

factors, including large increases in the prices of even generic drugs.³⁶⁸

One reason prices are substantially higher in the United States is that other countries have more centralized government payers negotiating prices or policies to restrict prices. A Brookings/USC paper estimates that sales in the United States account for two-thirds to three-fourths of global drug makers' profits, despite the country only accounting for one-fourth of global income.³⁶⁹

Overall, drug prices in the United States are more than twice as high as those in the United Kingdom.³⁷⁰ Compared to the United Kingdom, prices in America are double for Humira (used to treat arthritis), 42 percent higher for Harvoni (used to treat Hepatitis C), 89 percent higher for Truvada (used to treat HIV/AIDS) and over seven and a half times more for Tecfidera (used to treat multiple sclerosis).³⁷¹

Figure 5-2



Source: International Federation of Health Plans

MARKET FAILURES

Challenges of a Patent System

Inefficiencies and market failures in the pharmaceutical supply chain stymie innovation and drive up drug prices. For example, the uncertainty and long research times involved in drug discovery make it difficult for the private sector to fund research and development of pharmaceuticals.

The federal government issues patents, as well as markets exclusivities, and grants temporary monopolies to successful drug innovators as an incentive to conduct private investment in research and development (R&D). In effect, it delegates responsibility for providing a public good to a private company and compensates the company for doing so by allowing it to charge monopoly prices.

Contracting out a task that you cannot fully observe to an agent who has their own incentives creates what economists refer to as a “principal-agent problem.” Principal-agent problems can often be solved, but this requires sufficient monitoring and carefully designed rewards and penalties. Naively assuming that markets will deliver efficient outcomes in these situations is a recipe for inefficiency and abuse.

It is difficult to argue that this system for incentivizing drug discovery is achieving its goals in an efficient manner. One study found that the amount that Americans overpay (relative to other Western countries) on the top 20 drugs alone is more than one-and-a-half times what the drug manufacturers involved spend on R&D worldwide.³⁷² To maximize returns on their research investments, companies spend huge sums on marketing their

drugs. Only one of the 10 largest drug companies spends more on research than it does on marketing.³⁷³

The Role of Federally Funded Research

The federal government is involved in pharmaceutical R&D through funding research, providing tax credits, reviewing drug safety and ensuring patents and exclusivities. In particular, publicly funded research continues to be a large contributor to fundamental scientific discoveries. Private companies have an incentive to underinvest in “upstream” research that can be used for multiple products later on since some of the benefits of widely applicable discoveries will end up going to their competitors.

The government helps offset this underinvestment by investing directly in basic research. One study of 35 major drugs found that at least 80 percent were based on scientific discoveries made by public sector research institutions.³⁷⁴ Another study found that a one percent increase in publicly funded research led to a 1.8 percent increase in new drugs developed. In the same study, a one-time \$1 investment in public sector basic research yielded \$0.43 in benefits every year from then on, due to the development of new molecular entities.³⁷⁵

Public institutions are also now taking a more direct role in applied research. Estimates of the share of new drugs attributable to publicly-funded sources vary, but one study found that over nine percent of drugs approved by the FDA from 1990 to 2007 resulted from patents from public sector research institutions. These applications could also be more targeted toward the public good, as they are twice as likely as purely private applications to be granted priority review by the FDA. That means the FDA determined the drug would provide a significant improvement in safety or effectiveness in treating a serious condition.³⁷⁶

Non-Transparent Pricing

Pharmaceutical companies use complex price structures to extract as much money as possible from customers. The practice, known as price discrimination, would be impossible in a perfectly competitive market. The ability to conceal that pricing structure from other customers is a further departure from that ideal.

Manufacturers typically sell their drugs to pharmacies through a wholesaler. When the patient has insurance, they pay a copayment to the pharmacy that accounts for a share of the drug price. The insurer reimburses the pharmacy for the remainder of the cost of the medication. The insurer bargains with the pharmacy over the final price of the drug and may change the size of the copayment to encourage patients and doctors to opt for drugs that are more profitable for the insurer.

Additionally, the manufacturer may go around the pharmacy and wholesaler and offer rebates and incentives directly to the insurer. They do this to persuade the insurer to give their drugs better placement in the insurer's tier system, which means that plan participants will pay a lower copay for those drugs. This drives business toward those drugs instead of drugs made by competing manufacturers. The insurer, in turn, often negotiates coverage decisions with an employer or the government, rather than directly with the insured patient. Increasingly, the insurer may contract out the management of this process, and the bargaining involved, to another company, called a Pharmacy Benefits Manager (PBM).

The complexities and imperfections of the market for prescription drugs are partly caused and compounded by information asymmetries at several steps in the process. As with any aspect of the health care process, the patient has much less information than

the doctor, physician assistant or nurse practitioner about the correct treatment for their condition. The health care provider, in turn, will have less information than drug manufacturers about the effects of drugs, particularly newer ones. Manufacturers also have an information advantage over regulators such as the FDA, which does not see all the omitted research in an application to market a drug. Manufacturers have an incentive to selectively share information with regulators and to market their drug aggressively to health care providers and directly to consumers instead of providing unbiased information to both groups.

Markets that deviate from the ideal of perfect competition in so many ways require vigilance to prevent abuse, such as unfair price increases, and guarantee that existing and new products are delivered efficiently to the public.

Perverse Incentives in Supply Chains

The practices of drug manufacturers are only partly responsible for the high cost of prescription drugs. Prices that consumers pay are also the result of a series of negotiations among drug makers, health care insurers, wholesalers, pharmacies and PBMs.

The gap between the price of drugs before negotiations with the PBM and after price concessions remains large. In 2017, prices before negotiations increased by about seven percent, compared to about two percent after negotiations.³⁷⁷ These prices generally reflect a dynamic where manufacturers push sticker prices higher to improve their negotiating position, while insurers and PBMs attempt to extract the greatest concessions from manufacturers.

Perverse incentives, however, can lead multiple actors to attempt to generate greater profits by driving list prices higher and can be exacerbated by reimbursement structures in public insurance

programs. In general, the practice of charging different prices to different customers is always an indicator that a seller is exploiting some form of market power. The complex, opaque system of discounts and rebates can produce results that are good for profits but not good for consumers.

Anti-Competitive Practices

Research shows that competition generally leads to lower prices. Greater competition among brand-name drugs in a given therapeutic category and greater generic competition for a brand-name drug are both well-documented to lower prices. FDA research found that the first generic competitor only reduces prices slightly lower than the brand-name drug on average, but the second generic competitor reduces the price of the drug by nearly half. Further, drugs with nine or more generic competitors had an average price of 80 percent less.³⁷⁸

Unfortunately, there are more than 180 off-patent drugs without any generic competition. Some generics also may have no competition, as there are more than 500 drugs where brand-names have withdrawn from the market, possibly leaving only one generic.³⁷⁹

Egregious price increases, such as those involving Albuterol Sulfate and Digoxin, are enabled and exacerbated by lack of competition. The price for a bottle of 100 tablets of Albuterol Sulfate (used to treat asthma) increased from \$11 to \$434—a four thousand percent increase—in only six months. The price for a tablet of Digoxin (used to treat irregular heartbeats and heart failure) increased from \$0.11 to \$1.10 (an 884 percent increase) in less than two years.³⁸⁰ Such extreme price increases often occur when a manufacturer is the sole producer of a drug that treats a

small market. One example of this is the drug Daraprim, which is used for a rare, life-threatening parasitic infection.³⁸¹

Abuse of the Patent System

Brand-name companies engage in practices to create barriers to generic competition. Companies will extend the patent protection period for a drug by filing for additional patents on a certain aspect, such as methods of production, new formulations or new dosage schedules. One study found that almost 80 percent of drugs associated with new patents between 2005 and 2015 were existing drugs, not new ones. Nearly 40 percent of all drugs available on the market during that period added patents or exclusivities.³⁸²

Pay-for-Delay

Brand-name companies engage in other practices to block competition and maintain monopoly status. In pay-for-delay settlements, they pay generic companies to slow the introduction of a generic version of a drug, effectively extending the patent and preserving their monopoly. The Federal Trade Commission estimates that this costs consumers at least \$3.5 billion per year.³⁸³

Slowing the Development of Generics

Some brand-name manufacturers also attempt to block generic companies from accessing the samples of a drug they need to prove that their product is identical when they file generic drug applications to the FDA. Access is sometimes blocked by misusing FDA safety protocols intended to ensure that drugs are properly handled and distributed. One study found that access restrictions cost the U.S. health care system \$13.4 billion annually.³⁸⁴

“Gag Clauses”

Because of the lack of transparency in drug pricing and their efforts to charge different prices to different payers, PBMs inserted “gag clauses” into contracts with pharmacies to prevent pharmacists from notifying customers when the cash price of a drug they were buying would have been less than the copay required to purchase it through their insurance. Several states passed laws to ban this practice, and in 2018 Congress passed the “Patient Right to Know Drug Prices Act” and the “Know the Lowest Price Act of 2018” to eliminate this practice nationwide.³⁸⁵

Price Fixing

Generic companies also engage in anti-competitive practices. A massive antitrust lawsuit by the Attorneys General of 47 states and the U.S. Department of Justice alleges price-fixing by 16 generic drug companies encompassing over 300 drugs. Executives at one company pled guilty to conspiring to collude with other drug makers to divide up markets and keep prices higher. Investigators report that even a small fraction of the \$104 billion in total sales by generic-drug makers in 2017 would have cost consumers billions of dollars.³⁸⁶

Market Concentration

Mergers and acquisitions between companies that would otherwise be competitors generally result in less competition and higher prices. There is even evidence that mergers between large brand-name drug companies result in less R&D spending and fewer patents. According to a Government Accountability Office report, the number of mergers and acquisitions in the pharmaceutical sector held steady between 2005 and 2015, but the total value of the average deal went up, as did the number of deals

involving the 25 largest manufacturers.³⁸⁷ Market concentration is increasing in some drug classes.³⁸⁸

Medicare Part D

The federal government is the largest payer for pharmaceuticals in the United States through various government programs like Medicare and Medicaid, which together spend almost as much on pharmaceuticals as all private insurers combined. In fact, those programs comprised 40 percent of retail prescription drug spending in 2017, and that share is projected to grow to nearly 45 percent by 2026.³⁸⁹ Prescription drug costs have an outsized role in budgets for these programs. Drug spending in Medicare Parts B and D combined, which includes both physician-administered drugs and retail drugs, accounted for almost one-fifth (19 percent) of all Medicare spending in 2017.

The governments of other industrialized countries like Canada, Germany and the United Kingdom use centralized bargaining power to hold down pharmaceutical prices. In the United States, the Department of Veterans Affairs and the Department of Defense bargain with drug manufacturers to get a discount of approximately 50 percent relative to retail pharmacies.³⁹⁰

However, Medicare Part D is prohibited from bargaining on behalf of the American people. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which created Medicare Part D, prohibits the government-subsidized voluntary insurance program for prescription drugs for Medicare recipients from negotiating drug prices. The Republican majority in the 108th Congress passed this provision by bending House rules to hold votes open for hours to get the bill through the House and then to pass the conference report.³⁹¹

Unlike those in other countries, American regulators are not required to consider whether new drugs deliver better value for money than existing alternatives. The FDA does not even require applicants to submit pricing information with new drug applications and is doubtful of its legal authority to do so. Because of this, the FDA is unable to consider the price of a drug when it decides whether to grant the medicine market exclusivity.³⁹²

Foreign governments may be more effective shoppers than the U.S. government in other ways as well. Several other countries have agencies charged with comparing the effectiveness of new drugs—going beyond simply evaluating their safety and effectiveness. Those countries tend to spend less on expensive new drugs.³⁹³ While it is important to determine whether cost savings will result in slower adoption of useful new treatments, allowing more expensive drugs to enter the market without determining whether they are more effective than existing medication results in higher overall costs. Some countries balance these competing priorities by using different pricing mechanisms for old and new drugs.³⁹⁴

CONCLUSION

The *Economic Report of the President* fails to dig deeply into the causes of high prices for prescription drugs, pointing the finger at the FDA when in fact drug companies, distributors and insurance companies deserve much of the blame. As in other areas, the *Report* fails to recognize market failures even when they are obvious.

The patent system is often abused, stifling competition and driving up prices. Well-functioning, fairly regulated markets would lead to lower drug prices for millions of Americans. Conservatives—supposedly proponents of competitive markets—should take heed.

The federal government could help reduce drug prices by enforcing antitrust laws and outlawing anticompetitive behavior such as “pay-for-delay.” It could provide unbiased research into the cost-effectiveness of new treatments. In addition, it could learn from the example of other countries to negotiate lower prices and to counterbalance the market power of drugmakers.

However, the *Report* fails to grapple with market failures and other factors that drive up prices. Lowering the high cost of prescription drugs will require a better analysis of the root causes of the problem.