

THE HIGH COST OF PRESCRIPTION DRUGS IN AMERICA: *Is It Fair to Blame the Pharmaceutical Industry?*

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ABSTRACT

The United States of America spends an enormous amount of money on health care, a large portion of which is spent on prescription drugs. The problem is well known, but it is so severe that it merits regular re-analysis. Drug prices in the United States are higher than in other countries and many Americans struggle to afford them.

The price of prescription drugs is determined by multiple factors, most notably the pharmaceutical industry. This article explores the role of the industry from an objective, data-driven perspective, allowing readers to draw their own conclusions.

INTRODUCTION

America has a drug problem. The costs of prescription drugs continue to rise and can lead to noncompliance with medications because patients cannot afford them. Twenty-four percent of adults reported difficulty affording specific medications and 29% reported general noncompliance due to cost.¹

The United States spends more on health care than any other comparable nation, reaching \$3.8 trillion in 2019.² Health care spending accounts for 17.7% of the U.S. Gross Domestic Product (GDP) with retail prescriptions accounting for 10% of total spending, or \$370 billion.³ America's spending on pharmaceuticals greatly outpaces that of our international colleagues. According to estimates by the Commonwealth Fund, pharmaceutical spending per capita in the United States was \$1,443, about \$500 more than the next highest spender, Switzerland (\$939), and more than double that of Canada (\$613).⁴

There are two main contributors to total spending on prescription drugs: America's demand for medications and the rising costs.

As to the first, the number of filled prescriptions in the United States increased by 85% over the last two decades, despite the population increasing only 21% over the same period.⁵ Simply put,

more Americans are using more drugs – and this costs money. According to the Centers for Disease Control and Prevention, nearly 60% of adults aged 18-64 were prescribed medication in the past 12 months,⁶ reaching nearly 90% for adults aged 65 or older.⁷ Further, older Americans are more likely to take multiple prescriptions, with more than half taking four or more drugs.⁷

Volume is not the only issue, as Americans' prescription use is generally similar to that of Canadians⁸ and Japanese,⁹ but despite similar usage, Americans still spend much more per capita on pharmaceuticals than either of them. The reason is simple – higher prices.

It is axiomatic that noncompliance with prescribed drugs negatively impacts patients' health and increases total health care costs. A systematic review demonstrated that non-adherence to medication leads to three extra medical visits per year, and accounts for up to 10% of all hospital admissions.¹⁰ Noncompliance for cardiovascular disease alone may account for up to 125,000 deaths annually in the United States.¹¹ From a financial perspective, a report by the IMS Institute for Healthcare Informatics indicates that medication non-adherence is responsible for \$105.4 billion in avoidable health care costs.¹²

THE ROLE OF THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry (Pharma) has historically faced much of the criticism for the high cost of prescription drugs, but is it really to blame? There are often two sides to every story, and even this one is no exception. It isn't easy to defend Pharma; profits are high and CEO pay is substantial. However, Pharma counters that they assume great financial risk to develop new life-saving drugs, and they blame middlemen for the real problem.

The reader is invited to draw their own conclusions from the following objective, point/

counterpoint discussion, which is segmented into 3 P's – Products, Pricing, and Profits.

PRODUCTS

Point

It is axiomatic that Pharma is a great innovator, developing treatments for complex medical diseases that positively impact patients worldwide. Without their investment in research and development (R&D), countless patients would suffer due to a lack of innovation. Even the American public expects innovation by Pharma, as 71% trust the industry to develop new and effective drugs.¹³ Demonstrating their commitment to R&D, the top 10 pharmaceutical companies spent an average of 17.2% of their revenue on research and development in 2016, with two of them spending over 25%.¹⁴ These figures dwarf those of other industries, such as aerospace and defense, which invest 3% of revenues in R&D.¹⁵

The development of new therapies is risky, as many never make it to market or may arrive with multiple competitors. Of more than 7,000 drug programs in over 1,000 companies between 2006-2015, only 9.6% of drugs that entered clinical studies ultimately gained FDA approval.¹⁶ In another study, only 11.83% of drugs in clinical studies ever obtained FDA approval and reached the market.¹⁷ These two studies highlight the eventual failure of approximately 90% of new drugs that advance to human trials, with complete loss of the company's financial investment (Fig. 1).

The length of the R&D process – averaging 10 years from initial research to approval¹⁹ – also contributes to its high cost. An analysis of 63 drugs approved between 2009-2018 found a mean estimated cost of over \$1.3 billion, though smaller firms were likely overrepresented.¹⁹ An earlier study found the cost to be nearly double that, with estimated out of pocket cost per FDA-approved drug of nearly \$2 billion.¹⁷ Obviously, these expenditures must be recouped from approved drugs.

Counterpoint

The pharmaceutical industry clearly invests much in R&D, but the degree of investment may be misleading. The early phase of drug research is largely publicly funded and often occurs before Pharma enters the picture and initiates clinical trials. Of the 210 new drugs approved between 2010-2016, all

received public funding via the National Institutes of Health (NIH).²⁰ Of those, 84 were first in class with a new drug target or mechanism of action, demonstrating the important role NIH funding plays in innovation.²⁰

While Pharma has a role in R&D and in guiding initial research through expensive clinical trials, public funding is critical to new drug development. The industry and its shareholders are profiting from selling drug to the same Americans whose tax dollars helped fund development of their new drug.

Another way to look at Pharma's R&D investment is by comparing it with their marketing expenses, which are greater, in some cases much greater. A report by the Washington Post demonstrated that nine of the top 10 Pharma companies spend more on sales and marketing than R&D.²¹ A report by the U.S. House of Representatives Ways and Means Committee shows that during 2013-2017, the five largest U.S.-based pharmaceutical companies spent 70% more on marketing and administrative costs than on R&D.²²

PRICES

Point

The pharmaceutical company is only the first link in the long chain from manufacturer to patient; each link impacts the actual price a patient pays for a drug, and the pharmaceutical industry is not responsible for the final price due to the influence of "middlemen." Fig. 2 depicts the chain of wholesalers, pharmacy benefit managers (PBMs), pharmacies, and even the patient's insurer.

Pharmacy Benefit Managers act as middlemen, administering prescription drug benefit plans and negotiating discounts or rebates with Pharma that should benefit insurers, and which should enable insurers to reduce premiums. Since PBM contracts with insurers are confidential, it is unclear how much of the discounts obtained by PBMs get passed on to insurers and/or to patients. For Medicare Part D, the Government Accountability Office reports 99.6% of discounts negotiated by PBMs are passed on to drug plan sponsors, such as insurers.²⁴ Insurers have been accused of failing to pass these savings on to their subscribers, instead using the savings to increase profits.²⁵ The three largest PBMs, which control up to 90% of U.S. drug distribution, had an estimated combined

Drug Discovery and Development Timeline

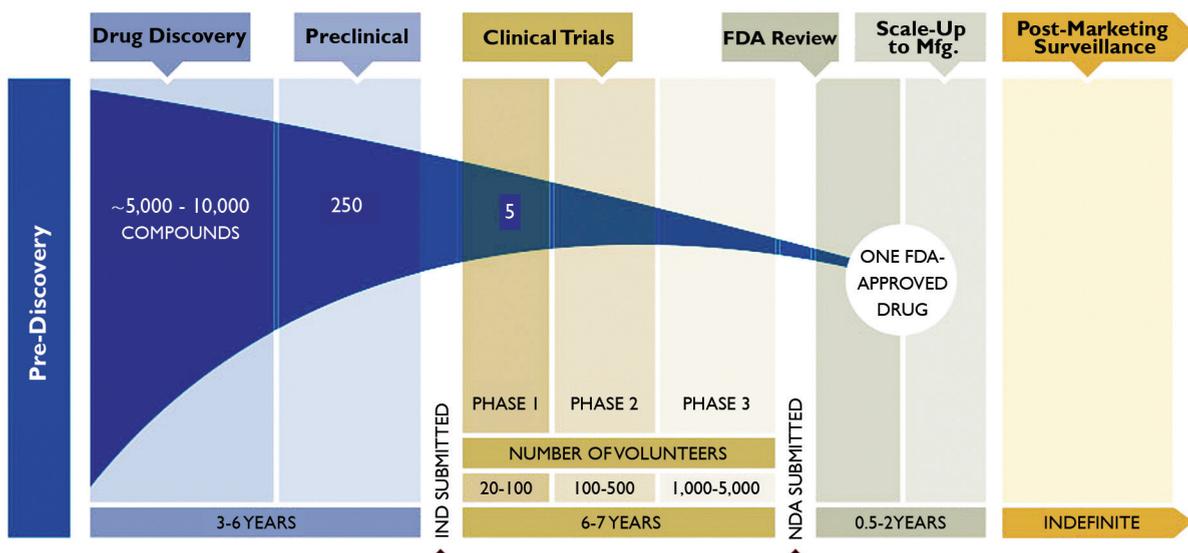


Fig. 1. There is a long timeline from discovery of a drug until it is marketed, and few drugs reach the final stage. (From the American Association for Cancer Research.)¹⁸

profit of \$17 billion in 2016.

While drug prices have seen periods of significant increases in the past, net prices paid by patients have stabilized somewhat, especially from 2015 to 2018, because discounts increased and now offset 62% of the increase in list prices, especially for Medicaid.²⁶ Pharma has also recognized that despite somewhat stabilized prices, many patients still have difficulty paying for drugs, and manufacturers have helped with savings cards, assistance programs, and donations of drugs. For example, Mylan Pharmaceuticals donated over 1,000,000 free EpiPens® to schools,²⁷ and Gilead Sciences pledged millions of bottles of Truvada® (emtricitabine/tenofovir disoproxil fumarate) annually to help uninsured Americans at risk for HIV.²⁸

In sum, Pharma points to the complex supply chain from Pharma to the consumer, and disavows much of the responsibility for high drug prices.

Counterpoint

Many prescription drug prices continue to rise, in certain instances at extreme rates. Though the actual price paid is often difficult to determine due to shifting formularies and the variety of rebates and discounts that may or may not be available to each

patient, it is clear that list prices have increased by 159% from 2007-2018, or 9.1% per year.²⁶ After taking into account any manufacturer concessions such as rebates or discounts, net prices still increased by 60%, or 4.5% per year.²⁶

While it is true middlemen may increase the price of drugs in America, pricing begins with the list price set by the industry. Like the MSRP for cars, the list price provides the basis for starting negotiations. Unlike other developed nations, the U.S. government is prevented from directly negotiating drug prices due to a “noninterference clause” in the Medicare Modernization Act of 2003.²⁹ Nearly 90% of Americans favor allowing the government to negotiate directly with the industry to lower drug prices,³⁰ an opinion also supported by the Biden administration but opposed by the pharmaceutical industry.³¹ House Bill H.R.3 of the 116th Congress, which passed the House in 2019 but did not receive a vote in the Senate, would require the Department of Health and Human Services to negotiate prices for certain drugs. The Congressional Budget Office estimates this would save \$450 billion over 10 years.³¹

Without government regulation or intervention, drug prices in the United States are free to rise

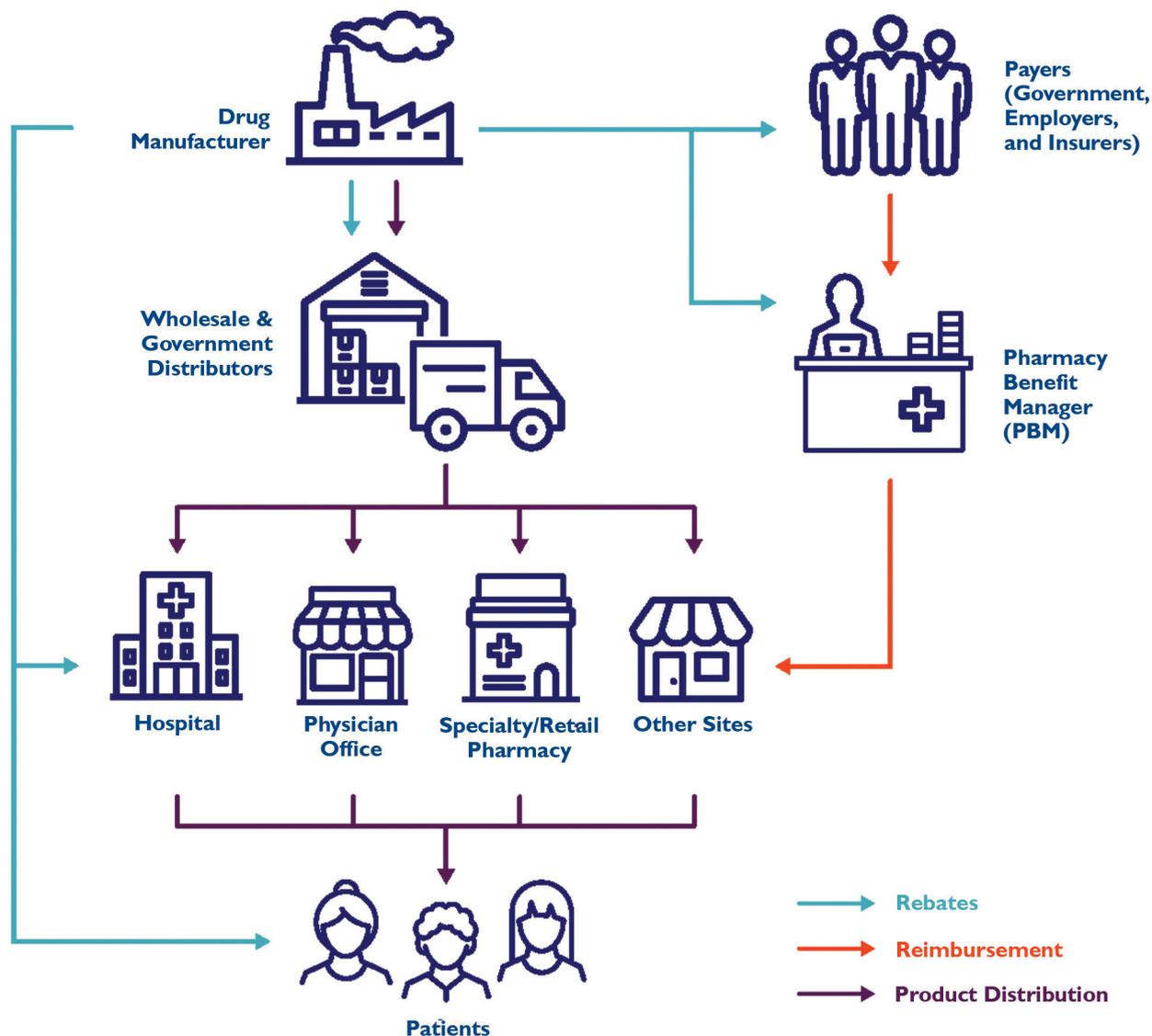


Fig. 2. **The Pharmaceutical Supply Chain.** The many steps between manufacture and consumption of a drug. (From the Commonwealth Fund.)²³

as pharmaceutical companies wish, leading to a situation in which American patients subsidize lower prices for others around the globe. Drug prices often increase at the start of each calendar year; in the first half of 2019, 3,400 drugs rose in price an average of 10.5%.³² In 2020, over 800 drugs increased in price, and in 2021 drug makers planned to increase prices for over 300 drugs.³³

In some cases price increases by Pharma have been extreme, seemingly for no other reason than to maximize profits. Humira® (adalimumab) is the

best-selling drug in the world, with nearly \$14 billion in sales in the United States alone.³⁴ Its price in the United States is five times the international average, and three times the price in the next highest-priced country.²² Over 97% of the top 100 Medicare drugs are substantially cheaper at Canadian online pharmacies.³⁵ Due to such price differences, 80% of Americans favor allowing drugs to be purchased from Canada where they are cheaper.³⁶ As a whole, Americans spend an average of three times more on drugs than those in Europe.³⁷ Even when accounting

for higher incomes, the United States still spends 90% more as a share of income.³⁷

There are many examples of massive price hikes, some of which have caught national attention. The list price of Mylan's EpiPen® has risen nearly 500% since 2009.³⁸ Despite a list price reaching over \$600 in 2016,³⁸ it reportedly contains approximately \$1 worth of epinephrine.³⁹ The most concerning price trend may be related to insulin, used by approximately 7 million Americans with diabetes.⁴⁰ An analysis by the House Ways & Means Committee found the average price per dose of insulin was 247% that of other countries.²² One study found that over a quarter of those surveyed reported underuse of their insulin due to the cost.⁴¹

Drug list prices in America are significantly higher than in other countries, as noted in Fig. 3. Estimates vary, but the U.S. government predicts approximately \$44.8 billion in savings to Medicare Part D alone if Americans paid a "basket list price" for drugs, defined as the average cost of 11 other comparable countries.²² This same report suggests an average 73% rebate would be required to match list prices in other countries.²²

Because Americans pay such higher prices compared to other nations, it is not surprising that 79% of adults say the cost is unreasonable.³⁶ Pharma may not be the only link in the chain between drug and patient, but they set the pace with their list prices.

PROFITS

Point

The U.S. economic system allows, indeed expects, profitability, and acknowledges the influence of supply and demand. Americans demand drugs and the industry provides them at a price the public has been willing to pay, if reluctantly. In addition, Pharma has a right to profit given their financial commitment to drug development and the financial risks associated with the R&D process. According to financial analysis by Sageworks, quite a few other industries enjoy greater profit margins than pharmaceuticals, such as accounting/tax prep and real estate.⁴² Without current profit levels, Pharma would be unable to maintain the large investment in R&D that is required to develop the new drugs that Americans need.

In addition, pharmaceutical companies are

critical to the nation's economy. The biopharmaceutical industry supports 4.7 million American jobs, and accounts for over a trillion dollars in economic output.⁴³ Further, the industry helps offset costs by offering savings programs and rebates.

Counterpoint

If there was any doubt about whether the industry's primary focus is people or profits, the former CEO of Valeant Pharmaceuticals made it clear in a 2014 interview with CNBC, stating "My primary responsibility is to Valeant shareholders."⁴⁴ Because of views like this, an overwhelming majority of Americans agree that pharmaceutical industry profits are the main contributor to the high cost of prescription drugs in America.³⁶

As expected, rising prices equate to rising profits and CEO compensation. The top 15 Pharma CEOs had a combined total compensation of \$266 million in 2019.⁴⁵ According to a 2017 report by the Government Accountability Office, pharmaceutical and biotechnology sales revenues have increased over \$200 billion in a decade – reaching \$775 billion in 2015.⁴⁶ Over this same period, approximately two-thirds of drug companies saw profits increase by an average of 17.1%.⁴⁶ This margin is even more remarkable when considering that profit margins of the 500 largest non-drug companies were only 4%-9% in one analysis.⁴⁶ A different analysis by West Health Policy Center that used Return on Invested Capital (ROIC – net operating profits after taxes, divided by invested capital) found that large pharmaceutical manufacturers had a 17.3% ROIC compared with 11.5% across other industries.⁴⁷ This same analysis suggests that large, brand name drug manufacturers could withstand a revenue reduction of more than \$1 billion and still have an industry-leading ROIC.⁴⁷ Thus, reforms to reduce prices – and therefore profits – would be manageable.

America is a critical market for Pharma due to the lack of price controls and the extensive use of prescription drugs. The American market alone is estimated to contribute 45% of total Pharma revenue despite only accounting for about 4.5% of the world's total population.^{48,49} Notably, the United States not only accounts for a disproportionate amount of revenue, but for an even greater degree of profit. A review by the Brookings Institution found that the United States contributes between

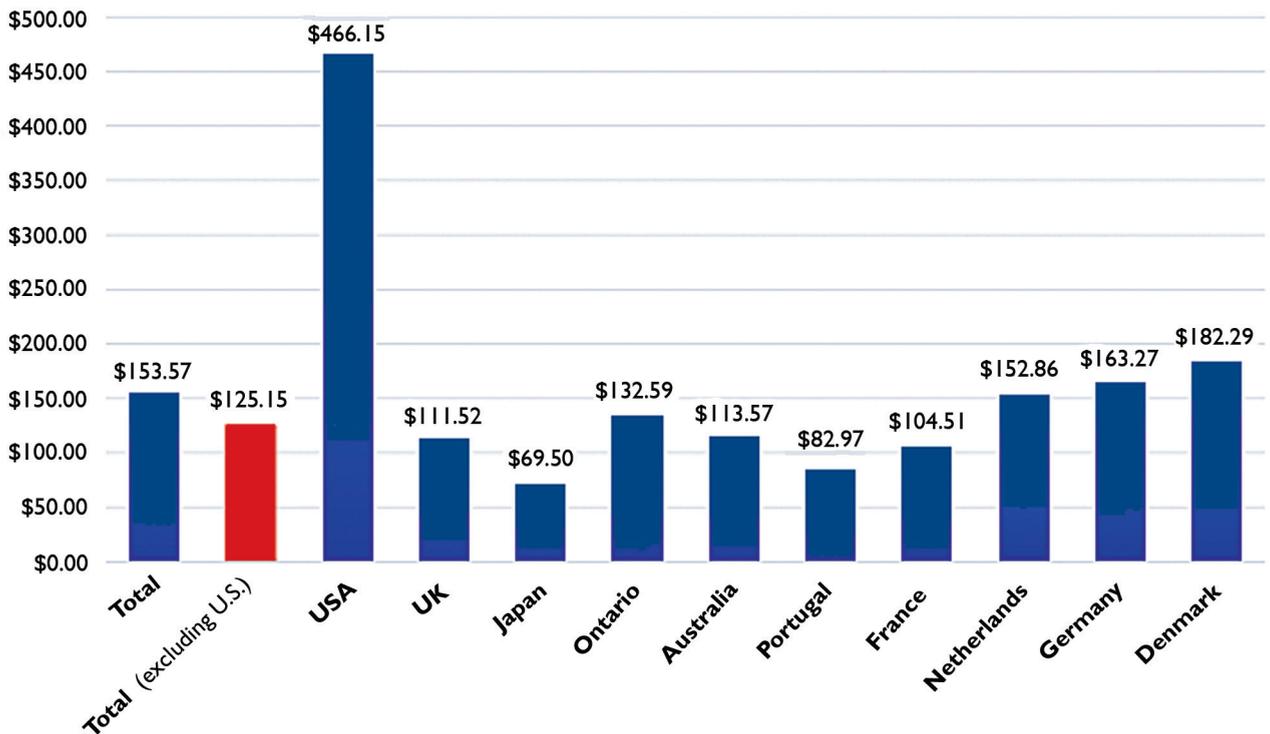


Fig. 3. Average List Prices for Drugs in Various Countries, 2018.
(From a report by the U.S. House of Representatives Committee on Ways and Means.²⁾)

64%-78% of global pharmaceutical profits,³⁷ thanks to the combination of extensive prescription drug use and high, unregulated prices.

CONCLUSION

The United States spends far more than any other nation on health care and prescription drugs, and prices are higher than in other countries. The pharmaceutical industry receives much of the criticism for high drug prices, but is this fair? By serving as innovators of new drugs and spending billions in the R&D process, Pharma might deserve more praise than blame, but the industry clearly plays a substantial role in setting high drug prices. Prices are higher in America than in any other country and continue to rise. Profits are soaring because American patients pay high prices for drugs whose development was supported by their own tax dollars. In fact, Americans are subsidizing industry innovation, as well as lower

prices in other countries. The industry's role in R&D is substantial, but may be exaggerated due to its support from public funding, and tax credits that offset costs.

Readers can decide for themselves how much blame the pharmaceutical industry deserves. Pharma takes on enormous risks in time and money to develop potentially life-saving medications. In America's capitalist economy, does this adequately justify the prices Americans endure and the profits they support? Is it more appropriate to shift the blame away from Pharma and onto others, such as PBMs or insurers? Perhaps we must also look at ourselves as a nation: How much is self-inflicted due to political gridlock that prevents potential solutions?

In the end, determining responsibility for the high cost of prescription drugs in America may be easier than developing a "prescription" to treat the problem.

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