



How International Reference Pricing for Prescription Drugs Would Hurt American Consumers

Joseph Fuhr, Liam Sigaud & Steve Pociask

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Rising drug prices continue to be a top concern of Americans. In response, members of Congress and officials at the Department of Health and Human Services have recently proposed imposing price controls on U.S. drug manufacturers by using what foreign countries pay for pharmaceuticals as a benchmark for what drug makers can charge in the U.S.



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Executive Summary

Rising drug prices continue to be a top concern of Americans. In response, members of Congress and officials at the Department of Health and Human Services have recently proposed imposing price controls on U.S. drug manufacturers by using what foreign countries pay for pharmaceuticals as a benchmark for what drug makers can charge in the U.S.

While these proposals may reduce drug prices in the short-term, as this study will show, their negative impact on consumers, pharmaceutical research, access to medicines, economic growth, jobs, and U.S. leadership in innovation would far outweigh their benefits. Artificially suppressing drug prices would substantially reduce incentives for drug manufacturers to invest in research and development (R&D) efforts to develop novel medicines – an undertaking that is estimated to cost nearly \$3 billion per new drug – resulting in fewer treatment options for patients. Price controls have never worked, because they lead in the short run to shortages and in the long run to decreased innovation.

The availability of cutting-edge medicines is far more limited in countries with price controls in their pharmaceutical markets. Of all new medicines launched worldwide between 2011 and 2018, the U.S. has access to nearly 90 percent of them. By contrast, countries – including those that would serve as a benchmark for U.S. drug prices – had access on average to only 47 percent of new drugs. Even when new drugs are ultimately approved in foreign countries, patients must typically wait more than a year longer than in the U.S.

Further, average household incomes in comparator countries are substantially lower than in the U.S., which calls into question the appropriateness of adopting their pricing practices. Since the willingness to pay for health care rises as income increases, tying American drug prices to the prices in lower-income foreign countries could deprive Americans of the choice to pay more for better health care. Adopting foreign drug prices would also constitute a tacit endorsement of the coercive practices – including compulsory licensing – that some foreign countries use to obtain heavily discounted drugs. This would undermine efforts to curb the abuse of American patents abroad.

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Adopting price controls from countries with socialized health care systems that artificially set below-market prices is the wrong public policy for achieving lower drug prices. Current and future generations would pay the cost of stifling innovation and curtailing access to life-saving medicines. Price controls cause shortages, which the empirical evidence in this study shows would limit patient access to innovative life-saving medications. American consumers care about having the U.S. be a leader in R&D, particularly with respect to producing innovative drugs. For example, a recent survey by The American Consumer Institute reveals that virtually all Americans (94 percent of heads-of-households) believe U.S. leadership in inventing and producing life-saving medicines is important.

Rather than stifle the free market, policymakers should be looking to harness competition and empower consumers to lower drug costs. Promoting transparency and competition in the pharmacy benefit manager (PBM) market, for example, has the potential to deliver billions of dollars in drug savings to consumers while preserving America's strong record of pharmaceutical innovation and access.

In summary, price controls will create shortages that would limit patient access to lifesaving medications, decrease market investment and jobs, undermine intellectual property rights, and squander the nation's position as a world leader in inventing and producing innovative drugs. A tradeoff often exists between competition with lower prices and innovation. The public policy issue is how to balance these dual objectives. Using international reference pricing to benchmark prescription drugs would be a major public policy failure with economic and public health consequences that would not easily be reversed.

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Introduction

Escalating drug list prices in the U.S. have generated a fierce political and policy debate. One approach to reducing drug prices for American consumers that is attracting considerable attention from policymakers is international reference pricing, the practice of pegging one country's drug prices to what other countries are paying for similar medicines.

Recently, several proposals to incorporate international reference pricing into U.S. law have been discussed. Legislation introduced by Senator Rick Scott (R-FL) and co-sponsored by Senator Josh Hawley (R-MO) would limit what U.S. drug makers can charge for drugs to the lowest price on the same drug in Canada, the United Kingdom, France, Germany, and Japan.¹ A similar bill, which would use the median price in those five countries as the benchmark for U.S. prices instead of the lowest price, has been introduced by Senator Bernie Sanders (I-VT) and Representative Ro Khanna (D-CA).²

The Department of Health and Human Services has also taken steps to adopt international reference pricing in Medicare Part B, which covers physicians' services for elderly Americans.³ In October 2018, Medicare -- which currently pays for drugs based on the average sales price in the U.S. market -- proposed to implement an International Pricing Index (IPI) to set pharmaceutical reimbursement rates, using prices in fourteen countries as a benchmark. Those countries include Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom.

All of these countries have implemented government-run health systems that impose price controls on drug manufacturers and stifle free-market mechanisms. As we shall see, these policies, while delivering lower costs to consumers in the short-term, have devastating long-term consequences in reducing life-saving pharmaceutical innovation and limiting access to cutting-edge medicines.

As more than 150 economists noted last year in an open letter to HHS Secretary Azar, adopting these misguided policies for the U.S. through an international reference pricing scheme would put American patients at risk.⁴ One reason that pharmaceutical prices are so

¹ Transparent Drug Pricing Act of 2019, S.977, 116th Congress, 2019, <https://www.congress.gov/bill/116th-congress/senate-bill/977>.

² Prescription Drug Price Relief Act of 2019, S.102, 116th Congress, 2019, <https://www.congress.gov/bill/116th-congress/senate-bill/102>.

³ "HHS Advances Payment Model to Lower Drug Costs for Patients," U.S. Department of Health and Human Services, October 25, 2018, <https://www.hhs.gov/about/news/2018/10/25/hhs-advances-payment-model-to-lower-drug-costs-for-patients.html>.

⁴ National Taxpayers Union, December 6, 2018, <https://www.ntu.org/library/doclib/2018/12/Economists-Letter-to-HHS-1.pdf>.

high in the U.S. is that the U.S. is subsidizing the rest of the world in the development of drugs. As we shall see, drug development is costly and other developed countries should pay their fair share of these costs. Indexing U.S. prices to those in other developed countries will not solve this problem, since other countries will not increase their prices to pay their fair share and the result will be less pharmaceutical innovation, including for American consumers.⁵

International Reference Pricing

Everyone wants to pay less for goods and services. However, drug prices do not exist in a vacuum, and artificially reducing prices through international reference pricing would have deeply negative effects on factors consumers value, such as access to treatments and the development of new beneficial drugs.

Governments in most other industrialized countries -- including those that some policymakers propose to use as a benchmark for U.S. drug pricing -- rely on government fiat and a “take it or leave it” approach rather than market competition to set pharmaceutical prices. These price controls could reduce drug makers’ revenues to levels close to direct production costs, leaving less funding for R&D investments into new medicines and reducing the incentives for R&D.

In contrast, the U.S. is a world leader in R&D in large part because its system of healthcare rejects price controls and encourages innovation. Consequently, a majority of new medicines are developed and launched in the U.S. Nurturing innovation is enormously beneficial to the well-being of Americans.

Price Controls: Bad in Theory, Disastrous in Practice

There is a long history of the many failures from price control policies.⁶ One notable example was in the early 1970s, when the Nixon Administration instituted its wage and price controls to slow the economy’s double-digit inflation. However, capping industrial prices led to cuts in market production which, in turn, led to shortages on such common consumer goods as meat and aluminum foil.⁷ Then-Treasury Secretary George Schultz observed these price controls would mean “low prices for food, but nothing to buy.”⁸ To confirm this point, one only needs to remember the long lines at the gas pump under gasoline price controls during the 1970s.

⁵ Erwin A Blackstone and Joseph P. Fuhr Jr., “The Complexity of Pharmaceutical Prices: An Economic Analysis,” *Journal of Commercial Biotechnology*, (Forthcoming).

⁶ Fiona M. Scott Morton, “The Problems of Price Controls,” *Regulation*, Spring 2001, p. 50-54, <https://object.cato.org/sites/cato.org/files/serials/files/regulation/2001/4/morton.pdf>.

⁷ The former White House Deputy Director of Consumer Affairs, William N. Walker, discusses shortages in “Forty Years After the Freeze,” July 2011, <https://nixonswageandpricefreeze.files.wordpress.com/2011/07/forty-years-after-the-freeze.pdf>.

⁸ R.W. Apple, Jr., “Nixon Freezes Prices for Up To 60 Days, Then Will Establish Phase 4 Controls; Farm Prices, Wages, Rents Unaffected,” *The New York Times*, June 14, 1973, <https://www.nytimes.com/1973/06/14/archives/nixon-freezes-prices-for-up-to-60-da-ys-then-will-establish-phase-4.html>.

As George Santayana once said, "those who cannot remember the past are condemned to repeat it." So it is, as many policymakers falsely perceive price controls as having some redeeming value and public appeal. After all, who does not want to pay less for the goods and services we enjoy? Do not the poor deserve protection from harsh price increases? Do drug companies really need all the money they make?

However, the free lunch of low prices is illusory. Price controls violate fundamental economic principles and end up doing more harm than good. When drug prices are held below market levels, drug production slows and shortages result, leaving doctors and hospitals with fewer innovative drug options for their patients.

In addition, low profitability will lead to resources being drained away from one sector of the economy to more profitable sectors. Redeployment of capital also means that the many talented scientists in drug R&D will seek careers in other fields. This disinvestment will dry up funding for state-of-the-art research facilities, resulting in fewer jobs and less discovery and innovation. All of this translates into fewer new and lifesaving drugs for patients. To borrow George Schultz's point – under price controls, there will be low drug prices but nothing to buy.

This is precisely what has happened in many foreign countries when drug price controls were put into effect. An analysis in 2018 by Precision Health Economics found that government price controls over prescription drugs in most industrialized nations (members of the Organization for Economic Co-operation and Development, or OECD) stifled innovation and markedly reduced longevity.

If government price controls in other OECD countries were lifted, the number of new treatments available would increase by 9%-12% by 2030 (equivalent to 8-13 new drugs in that year). For an individual aged 15-years-old today, lifting government price controls would increase life expectancy by approximately 0.8 to 1.6 years, and the lifetime welfare gains in health and quality of life — net of drug and medical spending and appropriately monetized— would amount to \$884 billion-\$3.15 trillion in 2060 across all OECD countries including the US.⁹

Reducing the Incentives to Innovate

By artificially suppressing prices, price controls trigger a host of unintended consequences. One of the most important of these is a reduction in the incentive for drug manufacturers to invest in R&D efforts to develop novel medicines.

The process of developing and manufacturing new drugs is costly and fraught with risk and uncertainty. For example, the average pre-approval R&D costs for new drugs and biologics have been estimated to be nearly \$2.6 billion. Counting post-approval R&D, average costs grow

⁹ Taylor T. Schwartz, et al., "The Impact of Lifting Government Price Controls on Global Pharmaceutical Innovation and Population Health," *Precision Health Economics*, May 2018.

to \$2.8 billion.¹⁰ Taking failures into account, the costs could be as much as \$5 billion for each new drug.¹¹ Only 12 percent of drugs that reach clinical trials get FDA approval, and only 30 percent of those become commercial successes.¹² For example, while 59 new drugs gained FDA approval last year, analysts warned that “the commercial potential of the class of 2018 is lacklustre.”¹³ Manufacturers commonly invest billions of dollars in research efforts that fail to produce any financial payoff.

In some therapeutic categories, R&D costs (and risks) are even more onerous. Over the last 18 years, there have been 75 unsuccessful efforts and only 3 new successful drugs for brain cancer.¹⁴ Between 2002 and 2012, the failure rate for new drugs targeting Alzheimer’s disease was 99.6 percent.¹⁵ Gene therapies, a new class of treatments that may provide cures to debilitating genetic diseases, are likely to be even more expensive to bring to market than traditional medicines.¹⁶

The costs of drug innovation are growing rapidly as the scientific underpinnings of drug development become more complex and FDA requirements become more difficult to satisfy. A recent study found that total capitalized development expenses have increased at a real annual rate of 8.5% from 2003 to 2013, resulting in an overall increase of 145 percent over a decade.¹⁷

To encourage the continued development of new drugs, economic incentives are essential. Drug makers must be confident and understand the likelihood that they will eventually recoup their costs and obtain a suitable return on investment. If manufacturers had not considered R&D spending to be a sound investment, many diseases for which effective treatments have been discovered would still not be treatable, hurting patients and making our society and the economy worse off.

¹⁰ Joseph A. DiMasi, et al., “Innovation in the pharmaceutical industry: New estimates of R&D costs,” *Journal of Health Economics*, May 2016,

<https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub>.

¹¹ Joseph Fuhr Jr., Liam Sigaud and Steve Pociask, “Novel Financing Approaches are Needed to Capitalize on Life-Saving Gene Therapies,” The American Consumer Institute, <https://www.theamericanconsumer.org/wp-content/uploads/2019/02/Gene-Therapy-FINAL.pdf>.

¹² Ibid.

¹³ Asher Mullard, “2018 FDA drug approvals,” *Nature Reviews*, January 15, 2019, <https://www.nature.com/articles/d41573-019-00014-x>.

¹⁴ Joseph Fuhr Jr., Liam Sigaud and Steve Pociask, “Novel Financing Approaches are Needed to Capitalize on Life-Saving Gene Therapies,” The American Consumer Institute, <https://www.theamericanconsumer.org/wp-content/uploads/2019/02/Gene-Therapy-FINAL.pdf>.

¹⁵ “Counting the cost of failure in drug development,” *Pharmaceutical Technology*, June 19, 2017, <https://www.pharmaceutical-technology.com/features/featurecounting-the-cost-of-failure-in-drug-development-5813046/>.

¹⁶ Joseph Fuhr, Jr., Liam Sigaud and Steve Pociask, “Novel Financing Approaches are Needed to Capitalize on Life-Saving Gene Therapies,” *ConsumerGram*, The American Consumer Institute, February 2019, <https://www.theamericanconsumer.org/wp-content/uploads/2019/02/Gene-Therapy-FINAL.pdf>.

¹⁷ Thomas Sullivan, “A Tough Road: Cost To Develop One New Drug Is \$2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less Than 12%,” *PolicyMed*, March 21, 2019, <https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html>.

By reducing the revenues manufacturers can expect to collect from new drugs, price controls sharply curtail R&D investment. A 2006 research paper by National Bureau of Economic Research analyzed data from 1986 to 2004 and found that restrictive price controls in the European Union (EU) relative to the U.S. had substantially dampened R&D spending by firms in the EU.¹⁸ Had EU R&D spending grown at a 6.6% annual rate (the rate at which U.S. R&D spending grew) instead of its actual growth rate of 5.4%, the paper predicted that 46 new medicines would have been produced and made available to consumers. Moreover, the authors estimated that if European-style price regulation had been adopted in the U.S. in 2006, the decline in R&D spending over the long-term would have resulted in 974 fewer new treatments and a loss of 1.6 million jobs. The health care quality we enjoy today would have been significantly reduced.

In 2005, economists at the National Bureau of Economic Research analyzed the effects of using price controls to cut pharmaceutical prices by 40 to 45 percent. They found that private firms would significantly reduce investments in R&D, resulting in a 50 to 60 percent decrease in the number of compounds moving from the laboratory into human trials.¹⁹ From the study:

*Because of the uncertainties involved, fewer compounds moving into clinical trials directly translates into fewer new products – the effects of which wouldn't be fully felt for several decades because of the long development cycle. Moreover, because of the spillover effects of R&D, less activity today reduces the possibilities for new opportunities in the future. Thus, these effects would likely compound themselves over time.*²⁰

According to a report on pharmaceutical pricing released by the White House Council of Economic Advisers last year:

*If the United States had adopted the centralized drug pricing policy in other developed nations twenty years ago, then the world may not have highly valuable treatments for diseases that required significant investment.*²¹

There is more at stake than just the amount of R&D spending invested in drug development or even the number of new medicines introduced (as important as those metrics are). There is evidence that the quality of pharmaceuticals, as measured by Quality Adjusted Life Years relative to the treatment's cost, also declines in price-controlled health care regimes.

¹⁸ Joseph H. Golec and John A. Vernon, "European Pharmaceutical Price Regulation, Firm Profitability, and R&D Spending," NBER Working Paper, November 2006, <https://www.nber.org/papers/w12676.pdf>.

¹⁹ Thomas A. Abbott and John A. Vernon, "The Cost of U.S. Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions," NBER Working Paper, February 2005, <https://www.nber.org/papers/w11114.pdf>.

²⁰ Ibid.

²¹ "Reforming Biopharmaceutical Pricing at Home and Abroad," White House Council of Economic Advisers, February 2018, <https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>.

As one example, researchers have found that Italy's price control system resulted in lower average drug quality relative to the U.S.²²

Pharmaceutical Shortages

By undercutting the drug industry's financial incentives to provide an adequate supply of medicines, price controls also cause drug shortages. In much of Europe, where single-payer health plans regulate pharmaceutical prices, the demand for drugs often exceeds the available supply, putting patients' health at risk. In 2014, the European Association of Hospital Pharmacists reported that 86% of hospital pharmacists agreed that medicine shortages were a current problem in the hospital where they work, with 3 in 4 clinicians saying that patient care had suffered as a result.²³

Drug makers and wholesalers naturally focus on markets where their products command the highest prices. The resulting disparity in drug pricing among European states creates opportunities for arbitrage, where "parallel traders generate profits through buying goods in one EU member state at a relatively low price and subsequently reselling them in another Member State where the price is higher."²⁴ In other member states, drug shortages are rampant.

In Slovakia, for example, government-imposed caps on drug prices have had devastating effect, as IHS Markit reported in 2013:

*Falling prices of some expensive prescription medicines in Slovakia is resulting in supply shortages, as levels of parallel exports from the country increase, reports Slovak medical news provider Mediweb. As the source reports, there are shortages in the supply of medicines used in the treatment of psychiatric and neurological disorders, epilepsy and other serious conditions, for which patients would not otherwise switch treatments, and for which there are no substitutes on the market. Thus, patients are being put at risk due to the increased levels of parallel exports. With prices of medicines in Slovakia – particularly originators – considerably lower than in a number of European Union countries, it is a lucrative activity for wholesalers, especially in view of the low prices which they face within the country itself.*²⁵

²² Vincenzo Atella et al., "Pharmaceutical Industry, Drug Quality and Regulation: Evidence from U.S. and Italy," NBER Working Paper, December 2008, <https://www.nber.org/papers/w14567.pdf>.

²³ "EAHP's 2014 Medicines Shortages Report Now Published," European Association of Hospital Pharmacists, November 17, 2014, <http://www.eahp.eu/news/eahps-2014-medicines-shortages-report-now-published>.

²⁴ Pat Treacy and Noel Watson-Boig, "What is Parallel Trade and How Does it Affect Pharma," Comp Law, December 1, 2016, <https://knect365.com/complaw-blog/article/073ed81f-0d17-4c0e-a819-38ff60332dec/what-is-parallel-trade-and-how-does-it-affect-pharma>.

²⁵ "Drug Shortages Resulting from Price Decreases Put Patients at Risk in Slovakia," IHS Markit, September 26, 2013, at <https://ihsmarkit.com/country-industry-forecasting.html?id=1065983235>.

Thus, even if drugs are bought at a low price in Slovakia, they can be exported to other EU countries where the price is higher. This has led to extreme shortages of drugs in countries like Slovakia. Ironically, the profits from this arbitrage do not go to the drug companies but parallel traders practicing arbitrage. To be sure, the U.S. is not immune to drug shortages. However, inefficient pricing is rarely the cause. Safety concerns, facility failures, and regulatory hurdles are more common culprits.

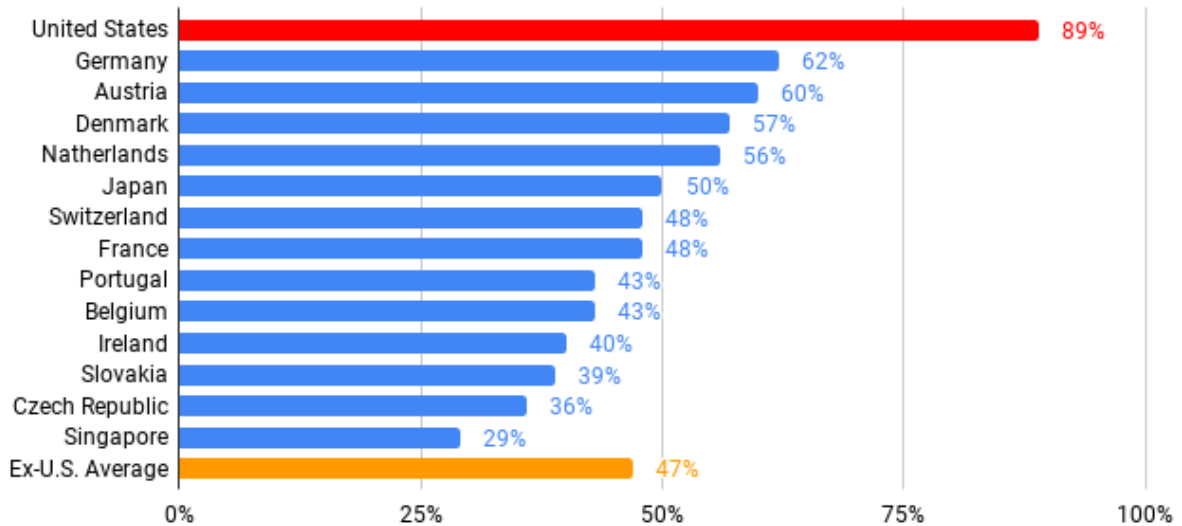
Restrictions on Drug Availability

In addition to chronic drug shortages that threaten the quality of health care available to patients, the pricing policies prevalent in most European countries have reduced or delayed the availability of new medicines.

Figure 1 below shows that, since 2011, the countries commonly cited as possible benchmarks for an international reference pricing system have lagged far behind the U.S. in making cutting-edge pharmaceuticals available to their citizens.²⁶ Of the 290 new medicines launched worldwide between 2011 and 2018, the U.S. has access to nearly 90 percent.

Figure 1: Number of New Medicines Available by Country (of 290 drugs launched worldwide 2011-2018)

Source: Galen Institute



Availability is far more limited in countries with price controls in their pharmaceutical markets. Germany had 62 percent of new medicines, Japan 50 percent, Ireland 40 percent, and

²⁶ Doug Badger, “Examination of International Drug Pricing Policies in Selected Countries Shows Prevalent Government Control over Pricing and Restrictions on Access,” Galen Institute, March 2019, <https://galen.org/assets/Badger-Report-March-2019.pdf>.

Singapore just 29 percent. Overall, comparator countries have access to fewer than half of all new medicines. If the U.S. adopts the prices of those countries, American patients may well face the same access restrictions that exist in those countries and lose access to existing treatment options.

The international disparity in access to drugs is even starker among therapies for cancer, which in 2012 claimed more than 8 million lives worldwide and continues to be a leading cause of death in the U.S. and throughout the world.²⁷ From 2011 to 2018, nearly all (96 percent) new oncology medicines developed were available in the U.S., compared to just 71 percent in the U.K. and 50 percent in Japan -- both countries which some U.S. lawmakers have advocated as benchmarks for drug pricing models.²⁸ The empirical evidence is clear; price controls restrict access to new life-saving medications for patients.

A 2017 study in the *Journal of Managed Care & Specialty Pharmacy* reviewed earlier data and found:

*Of 45 anti-cancer drug indications approved in the United States between January 1, 2009, and December 31, 2013, 67% (30) were approved [in Europe], and 53% (24) were approved in Canada and Australia before December 31, 2013. As of June 30, 2014, **in the United States, Medicare covered all 45 drug indications**, while the United Kingdom, France, Canada, and Australia covered 58% (26), 42% (19), 29% (13), and 24% (11) of that number, respectively. [Emphasis added.]²⁹*

Even when new drugs are ultimately made available in foreign countries, patients typically face long delays before they are available in that market. Figure 2 below shows the average (mean) number of months that elapse from a new cancer medicine's global first launch to its launch in a given country. Patients in the U.S. receive new cancer medicines faster than patients in any other country, with most developed countries taking years longer, if those drugs are made available at all. In addition, the variances shown in Figure 2 only tell part of the story, since they reflect only delays related to government regulation and do not consider delays linked to coverage and reimbursement approval. Thus, the disparities in access between the U.S. and other countries are even larger than Figure 2 indicates. In short, price controls in these countries contribute to delays in product availability that put patients at risk.

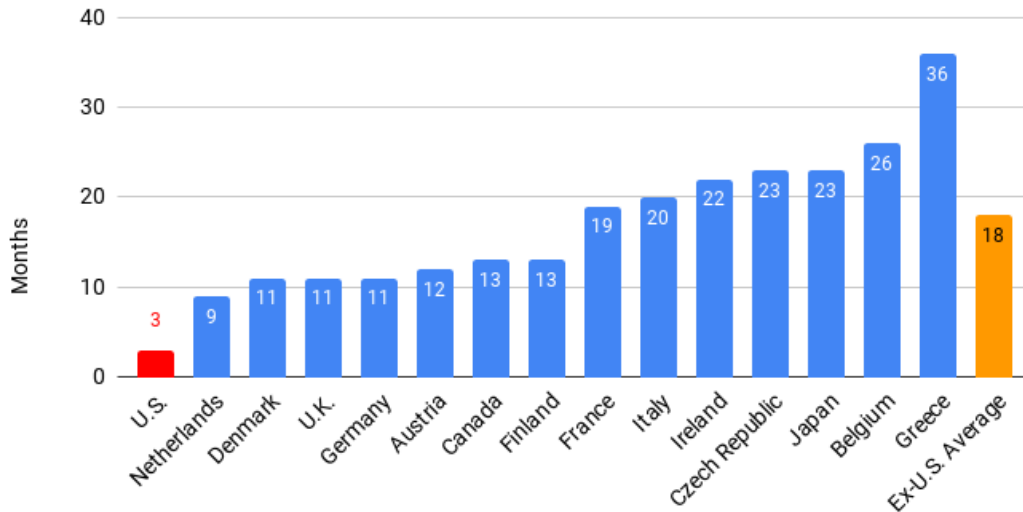
²⁷ "Cancer Statistics," National Cancer Institute, April 27, 2018, <https://www.cancer.gov/about-cancer/understanding/statistics>.

²⁸ "The United States vs. Other Countries: Availability of Cancer Medicines Varies," Pharmaceutical Research and Manufacturers of America, January 2019, data from January 2011 to September 2018, <http://phrma-docs.phrma.org/files/dmfile/IPI-Model---Comparison-of-Cancer-Medicine-Availability---012819.pdf>.

²⁹ Yuting Zhang et al., "Comparing the Approval and Coverage Decisions of New Oncology Drugs in the United States and Other Selected Countries," *Journal of Managed Care and Specialty Pharmacy*, February 2017, <https://www.jmcp.org/doi/10.18553/jmcp.2017.23.2.247>.

Figure 2: Average Delay in Availability of Cancer Medicines

Source: PhRMA analysis of IQVIA Analytics Link and FDA, EMA and PMDA data.



The international reference pricing models used in many European countries are largely responsible for these delays. A recent analysis found that repealing these regulations would reduce delays in Eastern Europe by up to 14 months per drug.³⁰

These delays matter to the sick and infirm. According to a study looking at non-small cell lung cancer (NSCLC), “if the access models representing five ex-US comparator countries (Australia, Canada, France, South Korea, and the United Kingdom) were to replace the actual US access conditions between 2006 and 2017, aggregate survival gains (i.e. gains in life years) due to innovative medicines would have been cut in half for US patients diagnosed with locally advanced and metastatic NSCLC. This reduction in health gains is due to the access delays experienced by patients in other countries compared to patients in the US.”³¹

The Partnership to Improve Patient Care has documented the experiences of numerous patients abroad trapped in countries where new medicines are not available:³²

It's devastating to not even be able to try a drug that could work for you... I understand a line has to be drawn but it feels unfair that other people make decisions about your life and how much it's worth.

-- Patient with breast cancer in the U.K.

³⁰ Luca Maini and Fabio Pammolli, “Reference Pricing as a Deterrent to Entry: Evidence from the European Pharmaceutical Market,” December 30, 2017, https://scholar.harvard.edu/files/lucamaini/files/reference_pricing_as_a_deterrent_to_entry.pdf.

³¹ Wayne Su, “Comparing Health Outcome Differences Due to Drug Access: A Model in Non-Small Cell Lung Cancer,” IHS Markit, December 13, 2018, https://cdn.ihs.com/www/prot/pdf/0119/IHSM_NSCLC%20HTA%20model%20white%20paper_18Jan2019r.pdf.

³² Partnership to Improve Patient Care, accessed April 24, 2019, <http://www.pipcpatients.org/access.html>.

There's no way I can't try this drug. It's the last thing that might save my life... It's crazy that I live in Canada, but now I'm looking at having to sell my house for coverage of my medication.

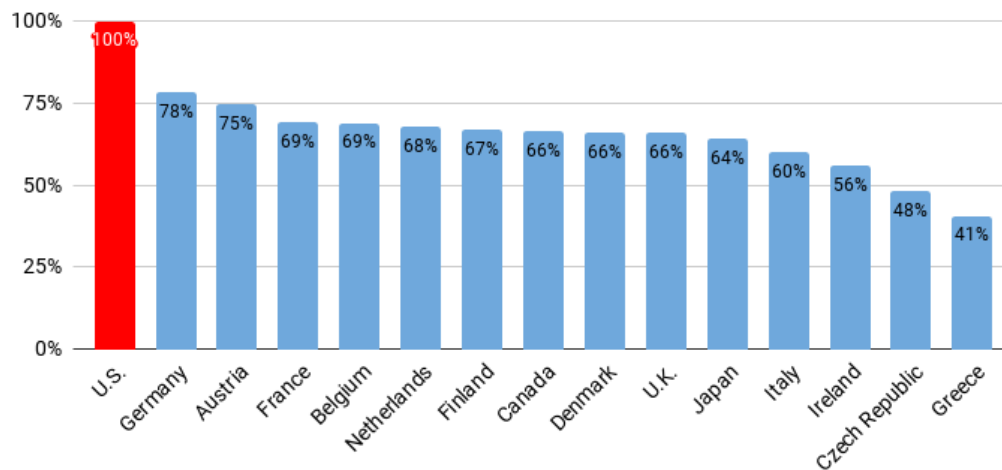
-- Patient with breast cancer in Canada

Economic Differences Between Countries

Significant economic differences exist between the U.S. and some of the countries advanced as models of drug pricing. One key difference, for example, lies in the level of relative living standards. As Figure 3 shows, none of the countries included in current international reference pricing proposals have household disposable incomes of more than 78 percent of the U.S. level, and two countries -- the Czech Republic and Greece -- that would be included in Medicare's pricing policies have disposable household incomes that are less than half that of the U.S. Are prices in these significantly lower income countries a reasonable guide for what prices in the U.S. should be?

Figure 3: Percent of U.S. Gross Adjusted Household Disposable Income (2016)

Source: Organization for Economic Co-ordination and Development (OECD)



It is well documented that as countries' average incomes grow, so does their willingness to pay for additional medical care.³³ By tying prices to countries with significantly lower living standards, American consumers who otherwise would be willing to pay more for better health care would be deprived of this choice. The income elasticity of demand for pharmaceuticals is greater than zero.³⁴ Thus, since the U.S. income is higher than other countries, consumers in the U.S. would be willing to pay higher prices on average for drugs than would consumers in other countries.

³³ Shirin Nosratnejad et al., "Systematic Review of Willingness to Pay for Health Insurance in Low and Middle Income Countries," PLoS One, 2016, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4928775/>.

³⁴ John Vernon and Rexford Santerre, "Own-Price, Cross-Price, and Income Elasticities, Private Consumer Demand for Pharmaceuticals," Center for Healthcare & Insurance Studies, University of Connecticut, February 13, 2014.

Intellectual Property and Economic Growth

Imposing international reference pricing on the U.S. drug market also raises concerns around intellectual property (IP) rights. Strong IP protections are central to U.S. innovation and economic growth. In 2016, the U.S. Department of Commerce found that, of 313 U.S. industries, the top 81 IP-intensive industries supported, either directly or indirectly, nearly 3 in 10 jobs and represented 38.2 percent of U.S. GDP.³⁵ In addition, wages in IP-intensive industries were 47 percent higher than in the rest of the economy. Exports from IP-intensive industries made up 52 percent of total U.S. merchandise exports and 12.3 percent of total U.S. private exports in services.

The pharmaceutical and medicine industry supports hundreds of thousands of high-paying jobs and is one of the most IP-intensive in the U.S. From 2009 to 2013, for example, drug makers acquired more than 20,000 new patents, a testament to the industry's status as a global leader. In addition, in 2014 pharmaceutical and medicine manufacturers ranked in the top three industries for merchandise exports, sending \$54.5 billion-worth of products overseas.³⁶

The U.S. is the leader in drug innovation and R&D, accounting for 60% market share in new active substances launched worldwide.³⁷ This leadership was spurred in large part due to the Bayh-Dole Act, which encouraged life sciences research in universities by giving these institutions Intellectual property rights to discoveries that were partly federally funded. Prior to the 1980 Bayh-Dole Act, U.S. global share for new active substances was in the single digits and the market was dominated by European rivals. The fact is that innovation and R&D suffer if not encouraged. Unlike the desirable impact of Bayh-Dole, the imposition of price controls would unquestionably dampen earnings and investments, which would decrease U.S. leadership in drug development and result in less innovation and a decline in consumer welfare. As our economy becomes increasingly knowledge-based, the importance of IP in delivering high-paying jobs to American workers and cutting-edge products to American and world consumers will only grow.

However, the abuse of American patents is a significant and growing problem. One of the strategies used by foreign countries is to threaten compulsory licensing, which allows IP to be expropriated without the owner's consent, to coerce U.S. drug makers to share their IP at heavily discounted prices. If drug makers refuse, nations simply ignore pharmaceutical patents and produce generic copies of the drug.³⁸ As a result, drug prices in Europe are often artificially

³⁵ The data presented in this paragraph come directly from "Intellectual Property and the U.S. Economy: 2016 Update," U.S. Department of Commerce, 2016, <https://www.uspto.gov/sites/default/files/documents/IPandtheUSEconomySept2016.pdf>.

³⁶ Ibid.

³⁷ For thorough discussion of this point, as well as historical data on global market share, see Stephen Ezell, "The Bayh-Dole Act's Vital Importance to the U.S. Life Sciences Innovation System," Information Technology & Innovation Foundation, March 2019.

³⁸ Comments to the Centers for Medicare and Medicaid Services, Center for Individual Freedom, December 28, 2018, <http://cfif.org/v/images/sections/CFIF-CMS-Comment-12.2018.pdf>.

deflated by abusing the IP rights of American manufacturers. Using these prices as a benchmark for U.S. drug prices would constitute a tacit endorsement of these abuses.

A recent survey commissioned by The American Consumer Institute in April 2019 found 88 percent of American heads-of-household strongly agree or somewhat agree that strong IP protections are vital to promoting innovation and creativity.³⁹ Similarly, the research found that 84 percent of heads-of-household agreed or somewhat agreed that IP protections would encourage research and development, and that, in turn, would create jobs and economic growth, according to 90% of those surveyed. These survey results are shown in Figure 4.

Figure 4: Survey Results on Patent Protections, Innovation, and Economic Growth

	Strongly Agree	Some-what Agree	Neutral, Neither Agree nor Disagree	Some-what Disagree	Strongly Disagree	Don't Know/ Other
Artists, authors, manufacturers and inventors use copyrights, trademarks, patents, and trade secrets to protect their products from counterfeiting and piracy. Do you agree or disagree that these protections are a good way to encourage innovation and creativity?	59%	29%	5%	2%	1%	5%
Do you agree or disagree that these protections encourage investment in research and development?	54%	31%	6%	3%	2%	5%
Do you agree or disagree that increasing research and development leads to increased economic growth and more jobs?	63%	27%	5%	1%	2%	2%
Do you agree or disagree with this statement: The U.S. is a world leader in research and development?	43%	31%	10%	8%	5%	3%
	Very important	Some-what important	Neither important nor unimportant	Not important	Don't Know/ Other	
How important do you think it is for the United States to be a world leader in inventing and producing life-saving medicines?	74%	20%	4%	1%	1%	

Source: “2019 Consumer Pulse Survey,” The American Consumer Institute, April 2019.

³⁹ Survey of 1,000 head-of-household fielded by American Directions Group on behalf of ACI, conducted April 2019.

As Figure 4 shows, when it comes to innovation in the pharmaceutical sector, virtually all Americans believe that U.S. leadership is important. While 74 percent thought that the U.S. was a world leader in R&D, an overwhelming 94 percent of heads-of-household thought that it was very important or somewhat important for the U.S. to be a world leader in inventing and producing life-saving medicines. The survey results provide clear evidence that the general public understands the importance of IP protection and its link to investment, jobs and economic growth, as well as the importance of U.S. being a frontrunner in drug innovation.

Legal protections for IP are foundational to the development of new drug treatments. For decades, American policymakers have tried to negotiate and enforce trade agreements with other countries that prevent IP theft. Instead of undermining these protections by importing the coercive practices of foreign countries, U.S. policymakers should safeguard the rights of patent holders and enhance the incentives for experimentation and discovery.

A Better Solution

There is no doubt that the drug prices many Americans face put a substantial strain on family budgets. However, instead of adopting radical price controls and importing the worst policies from abroad, policymakers should take proactive, market-based steps to reduce these prices without jeopardizing incentives for drug innovation and access.

1. Pharmaceutical Price Increases

While rapidly rising list drug prices have generated justifiable consternation from American consumers, net prices for drugs have actually decreased, making the use of list prices not that meaningful. For example, a report by Merck showed that during 2017 its net prices after discounts and rebates declined by 1.9 percent across its U.S. products, and Johnson & Johnson similarly reported that its net prices declined by 4.6 percent during 2017.⁴⁰ It is important to understand where these price increases come from and who benefits.

Drug manufacturers, as a whole, have not experienced growing profits. A recent study by the IQVIA Institute shows that drug makers' net revenues per capita -- after deducting all of the discounts and rebates they provide to pharmacy benefit managers (PBMs), pharmacies, and public health programs -- were just 6.5% higher in 2018 than in 2014.⁴¹ Over the same period, inflation in the overall economy, as measured by the Consumer Price Index, grew 6%, meaning that drug manufacturers, on a per capita basis, saw their revenues grow only slightly faster than overall prices over that period. Heightened market rivalry has also kept drug prices in check. It is estimated that generic drugs have saved in excess of \$1.67 trillion over a 10-year period and \$253 billion in 2016 alone.⁴²

⁴⁰ J. Loo and X. Choong, "Biotechnology." Standard and Poor's Industry Surveys, August 2018.

⁴¹ "The Global Use of Medicine in 2019 and Outlook to 2023," IQVIA Institute, January 29, 2019, <https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>.

⁴² "2017 Generic Drug Access and Savings in the U.S. Report" Association for Accessible Medicine, 2017, <https://accessiblemeds.org/resources/blog/2017-generic-drug-access-and-savings-us-report>.

Nearly all of the net increase in drug spending in the U.S. over the last few years has been driven by biologics -- large, complex molecules that are exceedingly expensive to bring to market and manufacturer, but with significant life-saving benefits.⁴³ Since 2013, spending growth on traditional, small molecule medicines has been modest and spending actually declined from 2016 to 2017 as competition from generic manufacturers intensified and prices dropped.⁴⁴

If manufacturers are not seeing rapidly rising revenues, why are consumers facing soaring drug list prices at the pharmacy counter? The answer, in large part, is that PBMs capture much of the difference between what consumers pay and what manufacturers receive. To be clear, consumers, insurers and hospitals are generally not paying the manufacturers list price, but prices set by the middlemen, PBMs.

2. How PBMs Increase Drug Prices for Consumers

PBMs administer prescription drug plans for sponsors (e.g. employers and insurers), negotiate drug prices with manufacturers, and negotiate reimbursement terms with pharmacies. As such, they serve as the middlemen of America's pharmaceutical industry. PBMs have been successful in decreasing the net price of drugs that they pay. However, since rebates are typically a percentage of the list price, retrospective rebates encourage higher list prices and PBMs favor the use of higher list priced drugs which yield greater rebates.⁴⁵

One commentator noted that it is similar to department stores raising prices before a sale to make the discounted price look more appealing.⁴⁶ Due to the lack of transparency concerning rebates, the issue that has arisen is how much of these rebates PBMs are passing to consumers and payers in the form of lower prices.

When a company hires a PBM to manage its employee prescription plan, it expects the PBM to act with the firm's best interest in mind. For PBMs, that would mean negotiating the best possible rates with manufacturers and pharmacies and passing those savings on to the plan sponsor and individual consumers.

However, for sponsors that hire PBMs, principal-agent problems occur. This is when the interests of the company and the PBM diverge and is a serious concern.⁴⁷ While a plan sponsor

⁴³ Avik Roy, "Biologic Medicines: The Biggest Driver Of Rising Drug Prices," *Forbes*, March 8, 2019, <https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicines-the-biggest-driver-of-rising-drug-prices/#4c0afe6f18b0>.

⁴⁴ "Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022," IQVIA Institute, April 2018, <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf>.

⁴⁵ Erwin A Blackstone and Joseph P. Fuhr Jr., "The Complexity of Pharmaceutical Prices: An Economic Analysis," *Journal of Commercial Biotechnology*, (Forthcoming).

⁴⁶ R. Feldman, "Why Prescription Drug Prices Have Skyrocketed," *Washington Post*, November 26, 2018.

⁴⁷ The economic literature is rich with research and discussion on the principle-agent problem. Among the Nobel Memorial Prize laureates in economics, see Joseph E. Stiglitz, "Principal and Agent," *The New Palgrave: A*

faces the direct financial costs of the particular prescription plan being offered to its members or employees, only the PBM has a complete understanding of the prices and costs flowing between the various players involved in prescription plans. The PBM's involvement in administering the prescription plan gives it unique insight into a series of opaque transactions involving sponsors, beneficiaries, pharmacies and manufacturers. These interactions among various parties create an environment for conflicts that drive PBMs to work for their self-interests, unbeknownst to the sponsor or beneficiary.

PBMs exploit this informational advantage to boost their own profits instead of maximizing savings for their clients.⁴⁸ They use a variety of tactics to achieve this goal. PBMs cut deals with pharmacies, promising them access to the plan's subscribers in return for cutting fees or reimbursement for what the pharmacies would normally earn for filing a prescription. This tactic, called spread pricing, adds additional profits for the PBMs over and above what plan sponsors pay PBMs for managing their plans. This profiting occurs without the sponsors knowing what the various negotiated and retail prices are and without knowing the recovery of pharmacy fees.

In addition, PBMs establish menus and tiers of drugs available on the plan – called a formulary. In establishing the formulary, PBMs negotiate prices with manufacturers, sometimes promising manufacturers higher volumes of drug sales in return for lower prices or promises to place formulary restrictions on competitors' products. Essentially, PBMs limit price competition in return for deeper manufacturer discounts and rebates. As before, the specific terms and conditions negotiated between PBMs and manufacturers are unknown to outside parties, including the pharmacies that fill the prescriptions and the plan sponsors.

Prescription plans often require beneficiaries (consumers) to cost-share through copays and deductibles. These sharing provisions are typically applied to the invoice or retail price for prescriptions. In recent years, there has been an increase in invoice prices for beneficiaries, accompanied with a much faster increase in manufacturer rebates for PBMs – all unbeknownst to plan beneficiaries. This means that consumers are paying more because of higher invoice prices, while PBMs are profiting more because of a surging increase in manufacturer rebates. The rebates are not flowing through to consumers in the form of lower prescription prices.

PBMs appear to be a major driver in the prescription price increases that distress consumers. As one expert writes, “most of the increase in drug spending were rebates pocketed by PBMs.”⁴⁹

Dictionary of Economics, vol. 3, pp. 966–71, 1987; and Kenneth J. Arrow, Uncertainty and the Welfare Economics of Medical Care, *American Economic Review*, vol. 53, pp. 941-73, 1963.

⁴⁸ Much of this discussion in the next three paragraphs comes from Steve Pociask, “Pharmacy Benefit Managers: Market Power and Lack of Transparency, The American Consumer Institute, 2017, <https://www.theamericanconsumer.org/wp-content/uploads/2017/03/ACI-PBM-CG-Final.pdf>.

⁴⁹ Robert Goldberg, “Drug Costs Driven by Rebates: Over \$100 Billion in Price Cuts Go Directly to Insurers, Not Patients,” Center for Medicine in the Public Interest, <http://bionj.org/wp-content/uploads/2015/11/drug-costs-driven-by-rebates.pdf>.

For example, if a manufacturer pays a PBM an incentive to offer a higher cost generic drug, by adding the drug to the plan’s formulary, the sponsor’s costs increase, as will the PBMs profits. This clear conflict of interest illustrates how PBMs do not necessarily represent the interest of the plan’s sponsors or their subscribers. Thus, the incentive for PBMs to do what is best for the plan and consumers is in direct conflict with the PBM’s incentive to profit.

There are many cases where generic drug prices are lower than plan deductibles. Since some plan beneficiaries do not know this and pharmacists, until recently, were not permitted to disclose this information, consumers were paying more than they should under their plans. The practice is called *clawbacks*, and it causes Americans to overpay on prescriptions by more than \$2 billion every year.⁵⁰ Once again, this illustrates that PBMs have incentives to keep prescription costs high, instead of working on behalf of the sponsors by lowering costs without sacrificing quality.

It should be clear who PBMs represent. By one estimate, PBMs fail to pass \$120 billion back to consumers, and retain another \$30 billion in additional out-of-pocket costs.⁵¹ Meanwhile, the market leader, Express Scripts, experienced an increase in net income from \$2.0 billion in 2014 to \$3.4 billion in 2016 – a 70% increase in profits in just two years. This comes in stark contrast with data from the Bureau of Economic Analysis showing that, across all industries, after-tax corporate profits have not increased over that period.⁵²

PBMs’ concentrated market structure also raises anti-competitive concerns. The three largest PBMs -- Express Scripts, CVS Health and OptumRx -- control about 72% of the market, enhancing their negotiating leverage and giving them more opportunities to extract additional revenues and profits.⁵³ Increased market concentration has reduced competitive pressures for PBMs to pass their savings through to sponsors or consumers in the form of lower prices. Therefore, while PBMs benefit, consumers are not benefiting from industry concentration.

According to one expert, “PBMs now realize more revenues than most drug manufacturers even though they engage in almost no innovation, bear little risk and, unless they own a mail order or specialty pharmacy, do not even take possession of the drugs.”⁵⁴

⁵⁰Karen Van Nuys, et al., “Overpaying for Prescription Drugs: The Copay Clawback Phenomenon,” USC Schaeffer Center, March 2018, https://healthpolicy.usc.edu/wp-content/uploads/2018/03/2018.03_Overpaying20for20Prescription20Drugs_White20Paper_v.1-2.pdf.

⁵¹ Jonathan Wilcox, “PBMs Must Put Patients First,” *Huffington Post*, February 28, 2017, https://www.huffpost.com/entry/pbms-must-put-patients-first_b_58b60bd8e4b02f3f81e44dcc?guccounter=1.

⁵² See Bureau of Economic Analysis data <https://www.bea.gov/national/pdf/SNTables.pdf>.

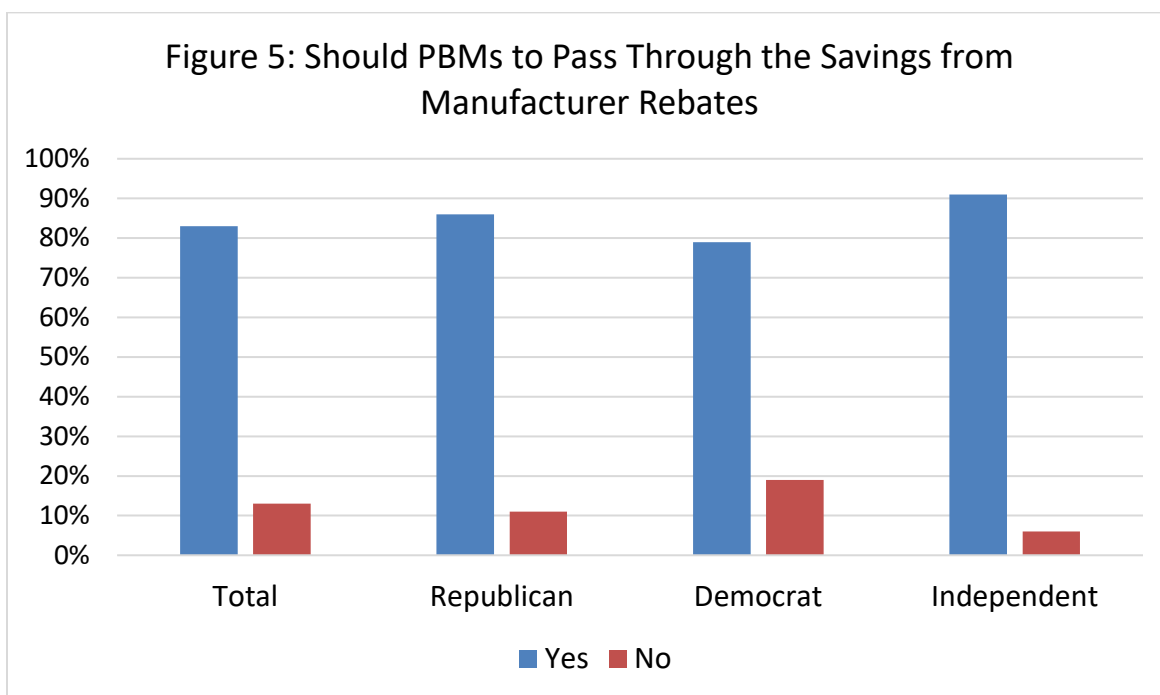
⁵³ Adam J. Fein, “The Outlook for Pharmacy Benefit Management: Evolution or Disruption?,” Drug Channels Institute, March 5, 2018, http://drugchannelsinstitute.com/files/PBMI-PBM_Outlook-Drug_Channels-Fein-Mar2018-Handouts.pdf.

⁵⁴ J. Shepherd, J., “Pharmacy Benefit Managers, Rebates, and Drug Prices, Conflicts of Interest in the Market for Prescription Drugs,” *Yale Law & Policy Review*, Vol. 38), 2019.

Cigna’s Express Scripts, CVS Health’s Caremark and United Healthcare Optum Rx have sales of over \$100 billion which places them in the top 25 on Fortune 500 and most large drug manufacturers have sales of less than \$50 billion.⁵⁵

3. *Creating Transparency and Accountability for PBMs*

Restructuring PBMs’ incentives to align with those of their clients would do much to lower drug costs for Americans. An April 2019 survey commissioned by The American Consumer Institute found that 83 percent of Americans -- including 86 percent of Republicans, 79 percent of Democrats, and 91 percent of independents -- believe the government should intervene to ensure that drug maker rebates paid to PBMs be passed through to consumers, insurers and hospitals in the form of lower retail prices (as shown in Figure 5 below).⁵⁶



To address the current market failures and anti-competitive risks in the PBM industry, the following public policy reforms deserve serious consideration:

⁵⁵ Ibid.

⁵⁶ For a discussion of The American Consumer Institute’s April 2019 PBM survey results, see Liam Sigaud, “Consumers Agree: Greater Transparency Among Pharmacy Benefit Managers is Needed,” *The Hill*, June 1, 2019. Specifically, the survey asked 1,000 heads-of-household the following:

“Pharmacy Benefit Managers price and administer prescription drug plans. These Pharmacy Benefit Managers also receive millions of dollars of rebates from drug manufacturers when they achieve certain volumes of sales. Would you support a law that would require these rebates to be reflected in lower prescription prices for patients at the pharmacy?”

- PBMs should provide the formulary, information on deductions and other out-of-pocket costs, and any administrative burdens (including pre-authorization requirements) to consumers and employers before they sign up for a plan;
- Patients paying coinsurance and/or deductibles should pay based on the negotiated price and not pay the full price for drugs;
- Pharmacies should be encouraged to disclose to patients when lower cost generics or over-the-counter medications are available outside of patients' drug plans;
- Pharmacists should be encouraged to disclose to patients when out-of-pocket costs are lower – if prescriptions are paid in cash instead of using insurance benefits; and
- In dealing with the flow-through of manufacturer discounts and rebates, the U.S. Department of Health and Human Services (HHS) or another government agency should be given federal auditing authority to collect the information necessary to measure the extent to which PBMs are flowing (or not flowing) additional revenues back to beneficiaries. This measure of pass-through should be made available to the public for each PBM on an aggregate level, without divulging specific confidential information.

Consumer prices are being intentionally inflated by PBMs that have failed to honor their fiduciary duties to their clients. The “light touch” regulatory remedies recommended here seek to reduce market power, increase transparency, provide consumers with more options, and heighten competition within the PBM market -- all without intrusive government involvement or counterproductive regulations.

Imperfect information is a market failure. In the face of asymmetric information where PBMs have better pricing information than plan sponsors and consumers, the goal of policymakers should be to allow consumers and sponsors to have the information they need to make better market decisions.

Some helpful reforms are already underway. The Department of Health and Human Services has proposed a new rule that would eliminate rebates from pharmaceutical manufacturers to PBMs in Medicare Part D and Medicaid managed care organizations, while creating regulatory incentives to increase discounts that directly benefit consumers at the pharmacy counter. The rule would also promote fixed fee payments from manufacturers for services (like favorable formulary placement) rendered by PBMs, rather than fees that are tied to list prices, volume of sales, or some other variable. This would do much to mitigate conflicts of interest that hurt consumers.

Finally, the rule would require PBMs to provide their plan sponsors additional details about their dealings with manufacturers, including the fees PBMs collect from manufacturers for services rendered.⁵⁷ If approved, these reforms, though confined to certain federal health

⁵⁷ “Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients,” U.S. Department of Health and Human Services, January 31, 2019, <https://www.hhs.gov/about/news/2019/01/31/trump-administration-proposes-to-lower-drug-costs-by-targeting-backdoor-rebates-and-encouraging-direct-discounts-to-patients.html>.

programs, would lower costs for millions of American consumers and demonstrate the benefits of broader transparency in the private PBM market.

Conclusion

Importing price controls from countries with socialized health care systems is the wrong approach to lowering drug prices for American consumers. Current and future generations would pay the terrible cost of stifling innovation and curtailing access to lifesaving medicines.

Instead, lawmakers should be seeking to bring transparency and competitive forces to bear on the pharmaceutical drug market -- and a good place to start is to reform regulations surrounding how PBMs operate. A more transparent, competitive PBM market could deliver billions of dollars in savings for consumers, without undermining incentives to invest in pharmaceutical R&D.

Lower drug prices are achievable but abandoning America's free-market system is precisely the wrong path and will have an adverse effect on consumers.