

BEFORE THE U.S. CONGRESS
HOUSE COMMITTEE ON EDUCATION AND LABOR
Subcommittee on Health, Employment, Labor and Pensions

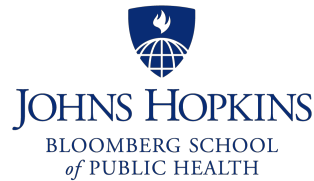
Congressional Hearing

" LOWER DRUG COSTS NOW: EXPANDING ACCESS TO AFFORDABLE
HEALTH CARE "

Statement of

Mariana P. Socal, M.D., Ph.D.

May 05, 2021



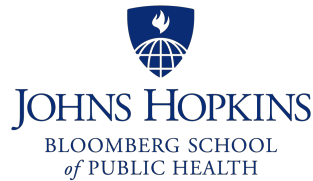
INTRODUCTION

Chairman DeSaulnier, Ranking Member Allen, and members of the Committee. It is a great honor to be speaking with you today. My name is Dr. Mariana Socal, and I am a medical doctor with a specialization in neurology. I also have a Ph.D. in Health Systems from the Johns Hopkins University and a master's in Public Policy from Princeton University.

I am currently a faculty member in the Department of Health Policy & Management at the Johns Hopkins Bloomberg School of Public Health. My primary research interest is how to improve drug access and affordability for people who need prescription drugs to improve their health and quality of life.

In the last few years, I have received funding to work with several large organizations that are attempting to control drug spending. These include PBGH, the Purchaser Business Group on Health, and ERIC-The ERISA Industry Committee. I have done extensive research examining the drug benefits that self-insured employers – from school districts to America's largest corporations – offer to their workers.

I am speaking today on my own behalf. The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University. I would like to provide commentary on how high drug prices impact American employers, their workers, and retirees.



PART I – HOW HIGH DRUG PRICES IMPACT AMERICAN EMPLOYERS, WORKERS, AND RETIREES

Most Americans obtain health coverage through their employers

Currently, over half of all Americans obtain health coverage through their employer¹ and one third are covered by employer self-sponsored health insurance plans.² This means that the prescription drug costs of most American workers are paid by employers and their employees.³ Both employers and employees are unhappy with the ever-increasing level of spending on drugs. In order to limit their spending, many companies are pushing more and more of the costs of prescription drugs onto the employees. This one of the reasons why members of Congress are hearing more about the cost of prescription drugs from their constituents.

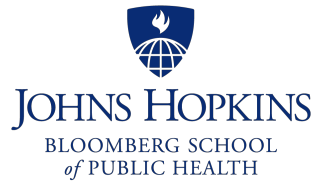
Self-insured employers take a financial risk to cover their employees

Given the high number of Americans who depend on self-insured employers to obtain their coverage, and the financial risk that these employers and employees are taking, it is imperative to keep prescription drug spending under control, not just for the public programs like Medicare and Medicaid, but also for the private sector.

¹US Census Bureau - Health Insurance Coverage in the United States: 2018
<https://www.census.gov/content/dam/Census/library/publications/2019/demo/p60-267.pdf>

² Kaiser Family Foundation Employer Health Survey 2018
<https://www.kff.org/health-costs/report/2018-emp-2018-health-benefits-survey/>
[https://www.kff.org/health-costs/report/2018-employer-health-benefits-survey/](https://www.kff.org/health-costs/report/2018-emp-2018-health-benefits-survey/)

³ Self-insured employers may purchase stoploss insurance, which may cover varying portions of the risk.
(reference: Kaiser Family Foundation survey)



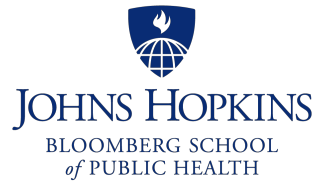
Today, prescription drug prices are on the rise and this means that many Americans are not able to afford the drugs they need, even if they have health insurance because of the out of pocket costs that are associated with many drugs.

Today, most employers negotiate drug prices through a PBM

The typical self-insured employer hires a pharmaceutical benefit manager – PBM – to manage their drug benefit. The PBM negotiates prices with drug manufacturers and, based on these negotiations, the PBM designs the drug formulary that determines the employer's drug benefits. PBMs cannot effectively negotiate lower prices for drugs when there is only one drug to treat a medical condition.

PBMs must have an alternative available in order to successfully negotiate drug prices

In order to obtain a lower price for a certain drug, the PBM offers to place that drug in a favorable position in the formulary – at lower cost sharing or without clinical requirements for utilization. A different drug is given a worse placement on the formulary and both drugs compete for the better placement by offering lower prices. Often, in exchange for a lower price, the PBM may agree to exclude the drug's competitors from the formulary. Therefore, the ability have alternatives and exclude certain drugs from the formulary is *crucial* for the success of most price negotiations performed by PBMs today. When the PBM has a choice, and therefore the ability to negotiate, the market can work. This occurs when there are both branded and generic products available in the market for the same drug, or when there are many

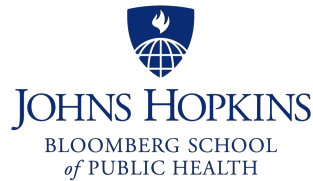


similarly effective drugs available in the market in the same therapeutic class to treat the same disease.

The market fails when there is no competition

The problem occurs when there is no competition because a certain drug is the only option available in the market. This may occur for new drugs. Of greater concern are drugs that have been on the market for a long period of time. In the United States prices tend to increase after the drug has been launched while in other countries the prices goes down. This is one reason why the prices for many blockbuster drugs are so much higher in the United States than other countries. Drug companies increase the prices in the United States and lower them in other countries.

Drugs can keep increasing their prices by keeping their competitors off the market. This can be accomplished by patent thickets, pay for delay, and other approaches drug companies use to keep generic or even other branded companies from entering the market. There are many different ways to do this but one approach is to add patent terms to the drug by implementing tweaks to the drug's original chemical composition, to the drug's administration mechanism, to the drug's method of use, and so on. Insulin, for example, is an unpatented drug used to treat diabetes. However, the devices used to administer the drug are protected by patents. It is not always the drug that gets the patent protection. Another example is EpiPen.



Drugs only work if people can afford them

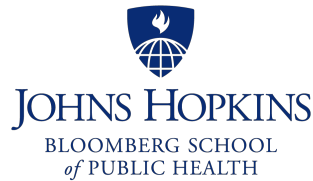
The positive impact from prescription drugs has been widely documented. Drugs can help save lives, prevent diseases, and improve quality of life. However, in order to obtain all these benefits patients must adhere to their treatments and take the drugs that they need in the correct dose and for the appropriate period of time as prescribed. When patients cannot afford their drugs, they cannot adhere to their treatments, and may develop complications. It is estimated that 3 out of 10 US adults did not take their medicines as prescribed in the last year because of the cost. Even more importantly, 1 out of 10 US adults experienced worsening of their condition as a result of not being able to take the drug as recommended.⁴

PART II – HIGH DRUG PRICES DISPROPORTIONATELY AFFECT US WORKERS AS COMPARED TO OTHER COUNTRIES

The US pays much higher prices than other countries for certain drugs

When the market is working the United States pays reasonable prices for drugs. Perhaps the best example is generic drugs, which represent 90% of all drugs sold in the United States. The prices for most generic drugs are comparable to international prices because there is competition. In other cases, there is no competition and the United States pays much higher prices for these drugs.

⁴ Kirzinger A, LopesL, Wu B, Brodie M. Kaiser Family Foundation Health Tracking Poll – February 2019: Prescription Drugs. March 01, 2019. <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>



My colleagues and I examined the 79 top-spending drugs in the Medicare Part D program that had no real competition because there were no generics or biosimilars available.⁵ These 79 drugs alone were responsible for over half of the Medicare Part D program spending in 2016. We compared the U.S. prices of these drugs to the prices in the UK, in Japan and in Ontario, Canada. We found that, on average, U.S. prices were 3 to 4 times higher than the prices in other countries, for the same drugs.

Other analyses have found very similar estimates. The Ways and Means Committee found that US prices were on average 3.7 times higher than the mean price of 11 other countries.⁶ Individual drug prices varied from 70% to 4,833% higher than the mean price in the other 11 countries. More recently, the Government Accountability Office found that US prices for 20 branded drugs were 2 to 4 times higher than in three comparison countries.⁷ Drugs with high prices have a number of similarities.

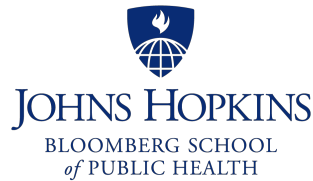
Drugs that have been on the US market for a long time have the highest price differentials when compared to other industrialized countries

While prices in other countries only go down over time, in the US, drug prices tend to go up. The result is that "older" drugs, i.e., those drugs that have been available in

⁵ Kang SY, DiStefano MJ, Social MP, Anderson GF. Using External Reference Pricing in Medicare Part D To Reduce Drug Price Differentials With Other Countries. *Health Aff (Millwood)*. 2019 May;38(5):804-811.

⁶ Ways and Means Committee. A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices. September 2019. https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf

⁷ Government Accountability Office. U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France. <https://www.gao.gov/products/gao-21-282>



the US for longer periods of time are the ones that have the highest price differentials when compared to other countries. In our study, for example, each additional year that a drug was in the US market was associated with a 33% higher price differential as compared to the UK, 25% higher price differential as compared to Ontario, Canada, and 17% higher as compared to Japan.⁸

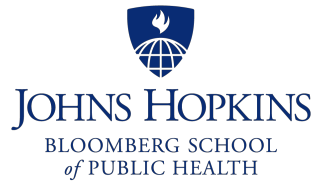
Drugs that have succeeded in continually increasing their prices in the United States, while lowering their prices over time in other countries are a big part of the problem. In January of 2021, a record number of 832 drugs raised their prices in the United States.⁹ 99% of these drugs were branded, and most of them had also increased their price for at least the last 2 years.

US drug rebates do not offset the price differential with other countries

Drug companies will argue that they do not get the prices they charge because some of this is taken up by rebates and other price concessions that they must give to get their drug on the formulary. One problem with this argument is that people often have their cost sharing based on the price the drug company sets for the drug and so when the drug company raises their prices the patient pays more.

⁸ Kang SY, DiStefano MJ, Socal MP, Anderson GF. Using External Reference Pricing in Medicare Part D To Reduce Drug Price Differentials With Other Countries. *Health Aff (Millwood)*. 2019 May;38(5):804-811.

⁹ Marsh T. 800+ Drugs Became More Expensive This January — The Largest Number of Increases in Years. GoodRX Blog. February 02, 2021. <https://www.goodrx.com/blog/january-2021-drug-increases-recap/>



Rebates can lower the prices paid by insurers. In our analysis, we accounted for drug rebates paid by drug manufacturers. We found that, in order for the US price to match the average price of the three other countries that we studied, drug manufacturers would have to offer in the US approximately 78% rebate, on average, for the 79 best selling drugs that we studied. This analysis was replicated by the Ways and Means committee and they estimated that the average US rebate would need to be about 73% in order for prices to match the average of the 11 countries that they examined.¹⁰ Drug rebates are confidential, and so it is not possible to verify manufacturer's actual behavior. However, it is unlikely that drug manufacturers would provide such high rebates to the drugs that have been studied because these drugs lacked direct competition. The numbers published by Medicare show average rebates for branded drugs in the low 20%.¹¹

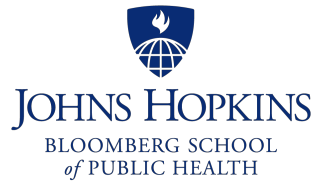
Prices before rebates determine Americans' cost-sharing amounts

Even if a manufacturer were to offer a large rebate to the PBM or self-insured company on one of these high-cost drugs, the problem is that the level of cost sharing by the American worker is determined by a drug's pre- rebates prices. The Associated Press reported in the first 7 months of 2018 that drug companies were 96 times more likely to increase the list price than to lower the list price.¹²

¹⁰ Ways and Means Committee. A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices. September 2019. https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf

¹¹ CMS. 2014 Part D Rebate Summary for All Brand Name Drugs. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/PartD_Rebates.html

¹² <https://www.apnews.com/b28338b7c91c4174ad5fad682138520d>



Americans are increasingly required to pay a percentage of the price of their drugs, especially for high-cost specialty drugs.

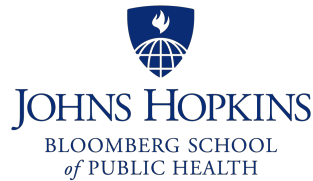
The amount that patients pay for high cost specialty drugs is frequently calculated as a percentage of a drug's cost. On average, patients pay approximately 22% of the cost of any given drug.¹³ This is why it is becoming increasingly hard for Americans to afford drug prices. Patients do not directly benefit from drug rebates because their out-of-pocket payment is typically calculated over the drug's price before rebates. Consider a drug costing \$2.1 million.¹⁴ It is for treatment of muscular atrophy, a disease that affects newborns and leaves them unable to walk. Parents are told there is a drug that could help your child walk, but the drug costs \$2.1 million and while the insurers will pay 80% of the cost you would still have a \$400,000 bill. How many young families can afford \$400,000?

Americans pay higher out-of-pocket costs for their drugs than patients in other countries

US insurers are paying higher drug prices than in other countries, and they are increasingly passing on these costs to consumer. As a result, US patients are also paying more out-of-pocket than people in other countries. While in Australia, for example, patients would pay either 5 or 28 dollars for a certain drug, the GAO

¹³ IQVIA institute. Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates. October 2016. <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/estimate-of-medicare-part-d-costs-after-accounting-for-manufacturer-rebates.pdf>

¹⁴ Fidler B. First oral drug for spinal muscular atrophy approved by FDA. Biopharmadive. August 07,2020. <https://www.biopharmadive.com/news/roche-ptc-risdiplam-approval-spinal-muscular-atrophy/583167/>



estimated that US consumers would pay between 22 and 514 dollars for the same drug in 2018.¹⁵

Out-of-pocket caps alleviate, but do not necessarily resolve the problem

Fortunately, there are out-of-pocket maximums for most employees with employer-sponsored coverage. However, in about 20% of cases, the out-of-pocket maximum is equal to or higher than \$6,000 a year.¹⁶ This amount represents almost 10% of the median household income in America (which, according to the US Census Bureau, was \$61,372 in 2017).¹⁷ In addition, patients pay full list price for their drugs while they are on their deductible phase; this is extremely important for the American workers enrolled in high-deductible health plans. As of 2018, 29% of workers with health insurance had high deductible health plans.¹⁸

Medicare beneficiaries do not have an out-of-pocket maximum

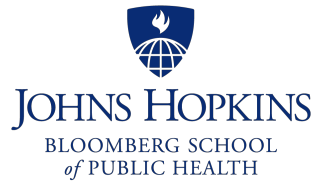
It should also be noted that, while most employees covered by employer-sponsored health insurance are protected by an out-of-pocket maximum, Medicare beneficiaries do not. Medicare beneficiaries obtain their drug benefit through the part D program, which does not have an out of pocket limit. There have been multiple proposals to

¹⁵ Government Accountability Office. U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France. <https://www.gao.gov/products/gao-21-282>

¹⁶ Kaiser Family Foundation Employer Health Survey 2018
<https://www.kff.org/health-costs/report/2018-employer-health-benefits-survey/>

¹⁷ US Census Bureau <https://www.census.gov/library/publications/2018/demo/p60-263.html>

¹⁸ Kaiser Family Foundation Employer Health Survey 2018
<https://www.kff.org/health-costs/report/2018-employer-health-benefits-survey/>



limit the out-of-pocket liability for Medicare beneficiaries; these proposals simply disagree on the amount of the out of pocket maximum.

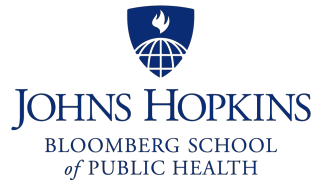
PART III – H.R.3 AND OTHER POLICY CONSIDERATIONS

High drug prices strain American employers, workers, and retirees. The market does not work for certain drugs because the PBMs, the main negotiators in the US system, have limited negotiating power when there is no competition. For these cases, alternative negotiation pathways are greatly needed. The negotiation mechanisms outlined in H.R.3 target these drugs for which there is a market failure. In the absence of product-to-product competition within the US market, the price comparison between the US and other countries can offer an alternative pathway for negotiation.

Using international prices as a benchmark can bring the US price back to international norms

Currently, most pharmaceutical manufacturers are global companies and they rely on sales in both US and international markets to obtain their revenue.¹⁹ Using average international market prices as a benchmark for US price negotiations will generate significant savings for US employers and their employees. Our analysis of the 79 top-spending drugs in Medicare part D found that, if the US paid the average price

¹⁹ <https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>



across the countries that we studied, savings would be \$72.9 billion dollars in 2018.²⁰ The Ways and Means Committee estimated \$49 billion in savings per year for Medicare Part D alone.²¹ If employers adopted this approach the savings would be similar.

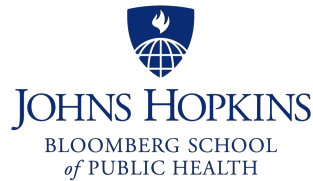
Other countries are unlikely to raise the prices that they pay for drugs; in fact, the prices keep getting lower. In the US, drug prices keep getting higher. There is no reason why the US should be paying 3-4 times what other countries are paying for the same drug.

Which countries should be included in the international price?

It is important to select countries that have similar per capita incomes and large pharmaceutical markets like the US. They can afford the expensive drugs. Ideally, these countries would also have diverse price-setting approaches. For example, some countries such as the UK have value-based pricing, whereas other countries such as Germany have market-based pricing. Our research found no major differences in the prices that are determined by the different approaches. Although countries may have different mechanisms for setting or negotiating drug prices, ultimately they obtain drug prices within the same price range.

²⁰ Kang SY, DiStefano MJ, Socal MP, Anderson GF. Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials With Other Countries. *Health Aff (Millwood)*. 2019 May;38(5):804-811.

²¹ Ways and Means Committee. A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices. September 2019. https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf



There is strength in numbers: price negotiations involving more individuals result in lower drug prices

Currently, negotiations for most covered Americans are fragmented. HR 3's proposal of having the HHS Secretary negotiate on behalf of all Medicare beneficiaries and those covered by private insurers, including by self-insured employers, would greatly increase the negotiation power because it would cover the vast majority of Americans. Combining larger numbers of individuals in a single negotiation has been shown to increase negotiating power and result in lower drug prices.²² In addition, companies can opt out of the negotiated price if they can get a better deal, which is a critical element of this proposal.

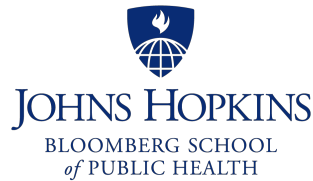
Experience suggests that the HHS Secretary can successfully negotiate prices

The experience of governmental agencies such as the Department of Veterans Affairs and the Department of Defense provides a solid example in support of the HHS Secretary successfully negotiating drug prices. These agencies have negotiated drug prices on behalf of their beneficiaries for years and have obtained the lowest prices in America today.²³ It is estimated, for example, that the VA pays 44% less than Medicare for a same basket of drugs,²⁴ and, the VA purchases a lot fewer drugs than Medicare.

²² Insurer bargaining and negotiated drug prices in Medicare Part D. Lakdawalla D., Yin W. NBER Working Paper 15330. <http://www.nber.org/papers/w15330>

²³ GAO-13-358. Prescription Drugs: Comparison of DOD and VA Direct Purchase Prices. <https://www.gao.gov/products/GAO-13-358>

²⁴ Venker B, Stephenson KB, Gellad WF. Assessment of Spending in Medicare Part D If Medication Prices from the Department of Veterans Affairs Were Used. *JAMA Intern Med.* 2019;179(3):431-433.



There is strong public support for allowing the HHS Secretary to negotiate drug prices

The Kaiser Family Foundation performs a periodic survey of the American public to examine the public's opinions, knowledge, and experiences on various issues related to the U.S. health care system.²⁵ In February 2019, the Kaiser Family Foundation survey found that 86% of the general public and 82% of Americans aged 65 and older supported allowing the federal government to negotiate with drug companies to get a lower price for people on Medicare. My own research has shown that 60% of older Americans would even trade off the possibility of choosing or changing a drug plan in Medicare Part D for more affordable drug prices.²⁶

Having the HHS Secretary negotiate drug prices would benefit employers

Currently, many Medicare prescription drug plans are managed by the same PBMs who manage the drug benefit for private plans, including for self-insured employers.²⁷ This means that when PBMs can't negotiate effectively for Medicare plans, they can't negotiate effectively for private plans, and vice versa.

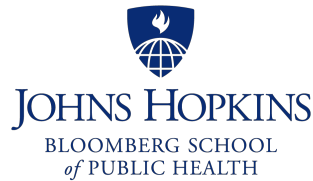
Employers need help getting good prices for high-cost drugs

²⁵ KFF Health Tracking Poll – February 2019: Prescription Drugs. <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>

²⁶ Social MP, Anderson GF.

Older Americans' Preferences Between Lower Drug Prices and Prescription Drug Plan Choice, 2019. *Am J Public Health*. 2020 Mar;110(3):354-356.

²⁷ Insurer bargaining and negotiated drug prices in Medicare Part D. Lakdawalla D., Yin W. NBER Working Paper 15330. <http://www.nber.org/papers/w15330>



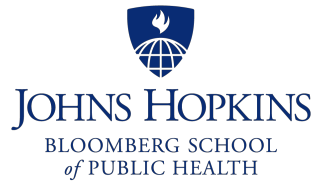
US companies, especially very large employers, like to think that they are getting the best possible deals from their PBMs. However, this is not always the case. We were asked by ERIC, the Committee that represents large nationwide employers who are also plan sponsors, to examine the prices that 10 of the largest US corporations were paying for biologics and biosimilars. The first thing that we found was that the PBMs did not always give these companies the information they needed to determine if they were getting a good deal. When we finally got the data, we found that two companies of the same size and using the same PBM were paying about 10% different prices for a same high-cost biologic drug.²⁸

Employers and workers are spending unnecessarily high amounts on branded drugs. Increased price transparency can help reduce that differential, but not eliminate it

PBMs have a financial incentive to keep high-cost, high-rebate drugs in their employers' drug formularies. This is because, for branded drugs, PBMs can make a profit by retaining some portion of the rebates plus any fees that they obtain from drug manufacturers, and drugs that are more highly priced can generally offer greater rebates. Therefore, drugs that have high prices and high rebates may be favored in the formulary in detriment of lower-cost alternatives. In the Medicare program, for example, we found that 70% of part D prescription drug plans had placed at least one branded drug placed more favorably in the formulary than its corresponding generic.²⁹ This increases cost unnecessarily for both plans and beneficiaries.

²⁸ These are initial results from an ongoing research project and have not been published.

²⁹ Social MP, Bai G, Anderson GF. Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available. *JAMA Intern Med.* 2019 Jun 1;179(6):832-833.



Unfortunately, employers do not always have the full information to identify that these distortions are present in their drug formulary.³⁰

Reducing wasteful spending from high-price high-rebate drugs could save employers up to 24% of their overall pharmacy spending

An analysis of 15 large US companies by the Pacific Business Group on Health, a purchaser coalition representing 60 public and private organizations across the U.S that collectively purchase healthcare for 10 million Americans,³¹ has shown that reducing the use of high-cost, low-value drugs could save 3% to 24% of a company's *overall* pharmacy spending.³² Having a transparent price for branded drugs available for all employers would increase transparency and would help employers identify where they are spending too much with certain drugs, better equipping employers to identify and ultimately remove wasteful spending from their drug benefit.

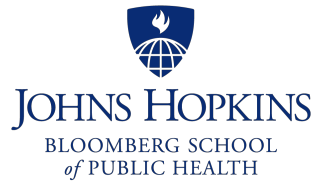
Having the option of accessing the HHS-negotiated price would benefit employers in two ways: lower drug prices and increased transparency

Having the option of accessing the federally-negotiated price would, first, offer lower prices to employers and to workers who obtain coverage through employer-sponsored health insurance. PBMs would still be allowed to negotiate down prices,

³⁰ Bai G, Socal MP & Anderson GF. Policy Options To Help Self-Insured Employers Improve PBM Contracting Efficiency. Health Affairs Blog. May 29, 2019. <https://www.healthaffairs.org/doi/10.1377/hblog20190529.43197/full/>

³¹ <http://www.pbgh.org/about/members>

³² Vela, L. Reducing Wasteful Spending in Employers' Pharmacy Benefit Plans. <https://www.commonwealthfund.org/publications/issue-briefs/2019/aug/reducing-wasteful-spending-employers-pharmacy-benefit-plans>



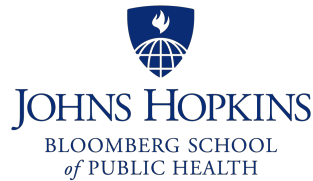
bringing additional price reductions into the system. The experience in the Japanese system, where the government negotiates a maximum price and payers obtain further discounts from their own subsequent negotiations, shows that drugs' actual selling prices will be lower than the maximum price in the government fee schedule because of competition among distributors.³³ In addition, HR 3 would benefit employers by providing them with a transparent maximum price. Having a transparent pricing benchmark will show employers if they are getting a better deal by opting in or opting out, improving their decision-making.

There is recent evidence that the government can negotiate prices for private purchasers

During the COVID-19 pandemic, the HHS Secretary negotiated prices for drugs and vaccines. The experience of the drug Remdesivir, an antiviral used at the hospital setting to treat COVID-19, provides a helpful example of how government-negotiated prices can be made available to private purchasers. In the case of remdesivir, the federal government allocated purchasing quotas to states and states were in charge of allocating these quotas to hospitals. Hospitals were in charge of purchasing the drug, when they could take advantage of the government-negotiated price, and were reimbursed by insurers accordingly.³⁴ Purchasing quotas were needed in this case because the supply of remdesivir was very limited. For branded drugs – especially those that have been in the US market for many years – it is unlikely that purchasing quotas would be needed.

³³ Ikegami N, Anderson GF. In Japan, All-Payer Rate Setting Under Tight Government Control Has Proved To Be An Effective Approach To Containing Costs. *Health Aff (Millwood)*. . 2012 May;31(5):1049-56.

³⁴ Social MP, Anderson GF. The Role of Advance Purchasing Commitments in Government Drug Price Negotiations: Lessons From the COVID-19 Response. *Am J Public Health*. 2021 Apr;111(4):652-657.



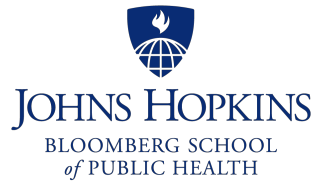
For patients, greater price transparency may reduce cost-sharing

Currently, when beneficiaries must pay a percentage of the drug cost, the patient's cost-sharing amount is calculated based on the drug's list price (i.e., the price before rebates and discounts are applied). The drug's net price after rebates and discounts is usually not known at the time that the patient is obtaining their drug and therefore it cannot be used. HR 3 will allow for HHS-negotiated prices to be available at the time that patients are obtaining their drug, allowing these prices to be used in cost sharing calculations. HHS-negotiated prices are likely to be much lower than the list price, which would likely translate to lower cost-sharing amounts for patients.

Having a penalty is an important element to enable the negotiation

The US pays more than other countries especially for drugs that have been on the market for many years. When drugs already have an established market, and there are patients who depend on them, PBMs are less likely to be able to say “no” and remove the drug from the formulary. Therefore, some drugs may exhibit egregious price-hiking behaviors such as Martin Skhreli’s Daraprim’s overnight 5000% price increase back in 2015 without concerns for losing market share.³⁵ It is important to have a clear penalty that can prevent these behaviors and ensure that drug manufacturers come to the table to negotiate.

³⁵ <https://khn.org/news/for-shame-pharma-bro-shkrelis-in-prison-but-daraprim-price-is-still-high/>



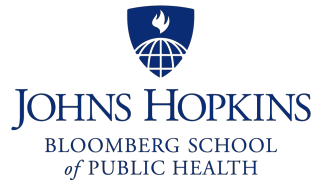
Having an inflationary rebate is an important mechanism to prevent price hikes for drugs that are not eligible or not selected for negotiation

Not all drugs will be selected for negotiation in a given time period. However, they may still exhibit price increases. H.R.3 establishes an inflationary rebate that provides an important mechanism to prevent such price increases for branded and generic drugs alike.

In order to protect and reward innovation, new drugs are granted patents that provide a period of time in which the drug has a monopoly i.e., no other competitor may enter the market. Drug manufacturers set the drug's launch price to allow them to recoup their research and development investments during the drug's monopoly period. Price changes that occur after a drug has launched are unlikely to be related to the need to recoup R&D investment. Other developed countries have mechanisms in place to prevent this type of behavior. In the US, many of today's high-cost drugs originally entered the market at lower prices and have only become expensive over time.

Negotiating price and quantity would offer an incentive for manufacturers to negotiate

The price negotiations established in H.R.3 represent an important tool to bring down drug prices, especially for drugs that have been in the US market for several years and have large price differentials with other countries. However, such price negotiation mechanisms are ineffective for drugs that lack any form of competition



or are not yet available in other countries. In such cases, the current PBM-based negotiation model and the H.R. 3 international-price proposed model might not necessarily provide effective tools for negotiation. An alternative negotiation tool could be to negotiate price and quantity simultaneously, such as through advance purchasing commitments.³⁶

Simultaneously negotiating both the price and the quantity of a drug may provide an incentive for drug manufacturers to participate in the negotiations and offer price concessions in exchange for increased revenue certainty. This is how retailers like Walmart are able to negotiate lower prices, and states have also sought such mechanisms when purchasing drugs. In addition, purchasing agreements established by the HHS Secretary with drug manufacturers during the Covid-19 pandemic provide examples of how such negotiations can be successfully implemented. The negotiation for the antiviral drug remdesivir achieved US price to government purchasers at the same level of prices offered to other countries, and prices to US private purchasers 33% higher than prices offered to other countries – a price close to the 120% established as the negotiation threshold by H.R. 3.³⁷

This experience also shows that the government does not have to actually purchase the drug but can simply guarantee a certain volume of sales. If the committed quantity were not to be realized over the defined time period, the federal

³⁶ The Role of Advance Purchasing Commitments in Government Drug Price Negotiations: Lessons From the COVID-19 Response. Socal MP, Anderson GF. *Am J Public Health*. 2021 Apr;111(4):652-657.

³⁷ The Role of Advance Purchasing Commitments in Government Drug Price Negotiations: Lessons From the COVID-19 Response. Socal MP, Anderson GF. *Am J Public Health*. 2021 Apr;111(4):652-657.



government could pay for the remaining negotiated quantity and utilize the leftover amount to provide care for specific programs or populations – such as uninsured patients or the prison system – or to stockpile it for future use. Finally, it allows everyone to have access to the drug at the negotiated price.

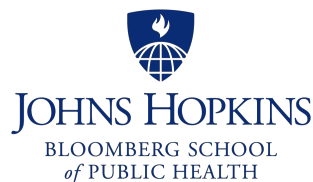
PART IV – IMPACT ON INNOVATION AND FOREIGN PRICES

Drug costs are unlikely to shift to other countries if the Secretary uses an international benchmark to negotiate prices in the US

Most developed countries have mechanisms in place to negotiate or regulate drug prices.³⁸ For example, the UK has a system of value-based pricing based on health technology assessment. In this system, a drug's benefits are compared to the other drugs that are available in the market for the same condition. The drug's price is then determined according to the value that the drug adds in comparison to its therapeutic alternatives. Such mechanisms are unlikely to be influenced by the US decision to include the country's price in the international benchmark. In addition, most countries already reference other countries' drug prices when negotiating or setting drug prices domestically.³⁹ Comparing prices to what other countries pay is not a new idea.

³⁸ Maniadakis N, Kourlaba G, Shen J, Holtorf A. Comprehensive taxonomy and worldwide trends in pharmaceutical policies in relation to country income status. *BMC Health Serv Res.* 2017; 17: 371.

³⁹ OECD Health Policy Studies. *Pharmaceutical Pricing Policies in a Global Market.* September 24, 2008. <https://www.oecd.org/els/pharmaceutical-pricing-policies-in-a-global-market.htm>



A potential unintended consequence of this practice, however, is that drug manufacturers could choose to delay⁴⁰ or not launch in a certain product in a given country - if they know the country will be used as a reference - in order to maintain the average price high. This is mostly a concern when including countries with less developed pharmaceutical markets in the international price. If only major pharmaceutical markets are included in the international price, manufacturers are highly unlikely to choose not to launch their product in that country.⁴¹ It is hard to keep Germany, Japan, France and the United Kingdom out of the market and only sell in the US.

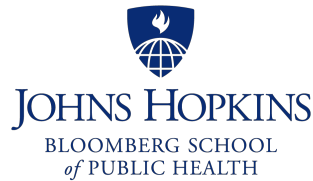
Allowing the HHS Secretary to negotiate drug prices is unlikely to significantly discourage drug innovation

The concern that negotiating prices would discourage innovation comes from the perception that, if pharmaceutical manufacturers were to have lower revenue, they would have insufficient funds or lack the incentives to invest in research and development of new drugs. In their analysis of H.R. 3, the Congressional Budget Office has estimated that about 8 fewer drugs would be launched in the US and the global market.⁴² However, it is unknown how truly innovative these drugs would be. The impact of price negotiations may be greater on less innovative or useful drugs. This may actually steer drug research and development into innovative areas. There

⁴⁰ Congressional Budget Office. Budgetary Effects of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act. December 10, 2019. https://www.cbo.gov/system/files/2019-12/hr3_complete.pdf

⁴¹ OECD Health Policy Studies. Pharmaceutical Pricing Policies in a Global Market. September 24, 2008. <https://www.oecd.org/els/pharmaceutical-pricing-policies-in-a-global-market.htm>

⁴² Congressional Budget Office. Budgetary Effects of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act. December 10, 2019. https://www.cbo.gov/system/files/2019-12/hr3_complete.pdf



is no reliable way to know what will happen, but we know that innovation is key to the branded companies and they will continue to innovate.

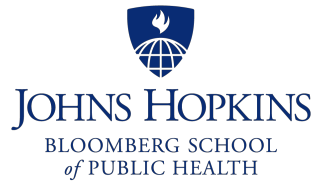
Without innovation, drug manufacturers have nothing to sell

Having a strong drug development pipeline is crucial in order to attract investors and remain competitive in the market. Companies like Pfizer, Merck, and J&J need to continually bring new products. A company that relies on US profits from its existing drug portfolio will be left behind by bold start-ups and foreign competitors if the company stops innovating. Claiming that controlling unreasonably high drug prices will hamper innovation flies in the face of how basic business and scientific incentives work.

Drug research and development is not the main reason for high drug prices

It is generally assumed that manufacturers set drug prices at levels that allow them to recoup drug research and development costs, not only of the drug in question but also for all other drugs that failed in the pipeline. However, there is growing evidence that research and development costs are not the main drivers of high drug prices.

In recent investigations, the House Committee on Oversight and Reform examined price-setting behaviors of different pharmaceutical manufacturers. These investigations have found that drug manufacturers often increased drug prices as a



response to low quarterly earnings and to increase executive compensation.⁴³ The expense of research and development has already occurred when the drug company raises its prices.

Under current prices, drug companies are able to recoup their investments in drug research and development multiple times over

Estimates suggest that, after four years in the market, most drugs will have generated over 9 times higher revenue than their own research and development costs.⁴⁴

High drug prices do not necessarily mean greater clinical value

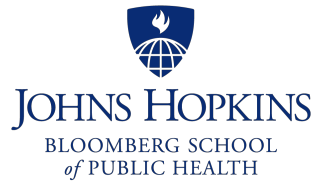
When evaluated for their safety and effectiveness in comparison to the other drugs available in the market, the vast majority - approximately 75% - of the specialty drugs sold in the US does not provide added therapeutic value as compared to conventional therapy. These are among the most expensive drugs in the US, and represent a large portion – about 15% – of Medicare part D spending⁴⁵

Public funds support a large proportion of drug innovation

⁴³ House Committee on Oversight and Reform. Committee Releases Additional Staff Reports on Skyrocketing Drug Prices for Day 2 of Landmark Hearings with CEOs. October 01, 2020. <https://oversight.house.gov/news/press-releases/committee-releases-additional-staff-reports-on-skyrocketing-drug-prices-for-day>

⁴⁴ Prasad V., Mailankodi S. Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval. *JAMA Intern Med.* 2017;177(11):1569-1575. <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2653012>

⁴⁵ DiStefano, M. J., Kang, S. Y., Yehia, F., Morales, C., & Anderson, G. F. (2021). Assessing the Added Therapeutic Benefit of Ultra-Expensive Drugs. *Value in Health*, 24(3), 397-403.



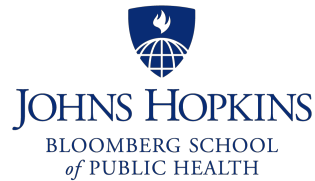
A large scientific literature shows that most new drugs originate as scientific breakthroughs from research funded by the federal government, though its agencies such as the National Institutes of Health (NIH). An analysis found that 97% of all new drugs approved by the FDA from 2010 to 2016 had received NIH support for the identification of the drug or its mechanistic basis.⁴⁶ The same study also found that 93% of the 100 most commonly prescribed drugs in the US had received NIH support. Government funding is especially critical at the initial phases of drug development, when failure rates are high. If the savings obtained from price negotiations were reinvested, governmental funding for drug discovery and development could be expanded.

Drug manufacturers spend more on advertisement than on drug development

Drug research and development costs represent a small portion of drug manufacturers' total spending. Pharmaceutical manufacturers spend more on drug marketing than they do on drug research and development. Nine out of 10 big pharmaceutical companies spend more on marketing than on research.⁴⁷ Even if manufacturer revenues were to decrease under the new policy, manufacturers would be unlikely to choose to cut spending on drug development when they could first implement cuts to the marketing budgets.

⁴⁶ Griesenauer RH, Moore R, Kinch MS. NIH Support for FDA-Approved Medicines. *Cell Chemical Biology* Volume 24, ISSUE 11, P1315-1316, November 16, 2017. [https://www.cell.com/cell-chemical-biology/fulltext/S2451-9456\(17\)30397-5](https://www.cell.com/cell-chemical-biology/fulltext/S2451-9456(17)30397-5)

⁴⁷ Swanson A. Big pharmaceutical companies are spending far more on marketing than research. <https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/>



FINAL REMARKS

High drug prices strain American employers, workers, and retirees. Because most Americans obtain health insurance through their employers, lowering US health care costs not only helps bring down premiums and out-of-pocket payments; lower health care costs also contribute to making American workers and corporations more competitive in the global market.

Thank you so much. I look forward to answering any questions that you may have.